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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION	**MDL No. 2741**
This document relates to all cases	**PLAINTIFFS' REPLY IN OPPOSITION TO ADMINISTRATIVE MOTION TO FILE UNDER SEAL AND RELATED MOTION TO MAINTAIN CONFIDENTIALITY**

Introduction

Monsanto needlessly requests relief from this Court to maintain confidentiality over a number of documents attached to Plaintiffs' response to Pretrial Order No. 8 ("PTO 8"). In its February 13, 2017 Response, Monsanto made two requests: (1) that the Court allow nine (9) documents and a portion of Donna Farmer, PhD's deposition testimony to remain under seal; and (2) that the Court enter an order prohibiting Plaintiffs from attaching discovery documents to "motions or other filings" regarding discovery or case management issues absent a specific request from the Court.[1] To be clear, this request by Monsanto even includes documents not designated confidential. Monsanto's request that the Court

[1] This Motion violates local rule Civ.L.R. 7-2 and is not properly before the Court.

limit or prohibit Plaintiffs' ability to use documentary evidence to support theiprosecution of this matter is offensive, violates Plaintiffs' due process, and is a red herring meant to distract the Court from the real issue: Monsanto has designated over 85% of it s documents confidential (thousands of which are wrongfully designated and are embarrassing or demonstrate company misconduct) and Monsanto wants to keep those non-confidential documents hidden from the public. Last week, and in complete contrast to the negotiated Protective Order, Monsanto created the term "litigation need" and filed a discovery letter requesting that Plaintiffs only be allowed to challenge confidentiality designations after proving a "litigation need." Now, Monsanto has taken its request even further and is requesting the Court prohibit Plaintiffs from attaching *any* documents produced in discovery (whether designated confidential or not and whether produced by Monsanto or not) to *any* "motion[] or other filing[] regarding discovery or case management issues." See, Proposed Order Dkt. 143-2. This request is transparent and for the reasons set forth below, this Court should deny both of Monsanto's pleas.

A. Plaintiffs' Exhibits Are Not Confidential and Are Directly Responsive to PTO 8

Plaintiffs' use of exhibits to support their response to PTO 8 is specifically responsive to the Court's directive that the parties "submit briefing discussing: (1) whether alleged flaws and/or biases in EPA or IARC methods, studies, reports, or conclusions are relevant to general causation; and (2) if so, what material is needed to assess allegations about those flaws and/or biases."Dkt. 120. Thus, Plaintiffs submitted exhibits to support factual statements that, if left uncited, could be considered baseless, thus hindering Plaintiffs' arguments. Moreover, and contrary to Monsanto's accusations, in deciding to use each exhibit, Plaintiffs considered and accounted for Monsanto's right to maintain confidentiality over trade secrets and other confidential business information.

As set forth fully in Plaintiffs' PTO 8 briefing, the exhibits are directly relevant to bias in EPA's methodology because they show Monsanto engaging in a pattern of selective submission of information, ghostwriting, and other efforts that injected biases or flaws into EPA's review of glyphosate. On the other hand, Monsanto frames the Court's PTO 8 inquiry as a "purely legal question"despite the fact that

the inquiry necessary called for a discussion of alleged "flaws and/or biases" in IARC or EPA's "methods, studies, reports, or conclusions"—proof of which requires a factual showing.

Thus, Monsanto reads the Court's inquiry contained in PTO 8 too narrowly. The question presented is whether: "alleged flaws and/or biases in EPA or IARC methods, studies, reports, or conclusions are relevant to general causation . . . ." See, PTO 8. As argued in Plaintiffs' PTO 8 Briefing, IARC's analysis is tantamount to a general causation analysis, while EPA's conclusions are limited to a "risk assessment." Plaintiffs are entitled to explain why they are making this assertion; in fact, the Court specifically requested briefing on this issue. Each and every exhibit attached by Plaintiffs to its PTO 8 Briefing is directly relevant to Plaintiffs' argument. Contrary to Monsanto's assertion, Plaintiffs did not opportunistically attach documents for the sole reason of harassing or prejudicing Monsanto; but rather, selectively chose documents in support of their argument. By way of example, Monsanto argues that Plaintiffs' Ex. 9, comprised of two email chains, should remain under seal because they show "employees strategizing regarding a potential meeting with the [EPA]" and "[p]ublic disclosure of this document would cause harm to Monsanto by revealing Monsanto's internal strategies and processes for assessing potential scientific and regulatory actions and its approach to communications with the EPA." Dec. of Robyn D. Buck at 4, ¶ 6 [Dkt. 143-1].

Putting aside that communications with a federal agency should not be confidential, and contrary to Monsanto's characterization of Ex. 9, this email chain actually shows that the EPA requested Monsanto submit additional studies regarding glyphosate because the EPA was concerned about flaws in its pesticide registration analysis following IARC's classification of glyphosate as a 2A carcinogen. There is nothing confidential about this request from EPA nor is there any reason to think that public disclosure of any such a request directed toward Monsanto would cause it competitive harm. Here, Monsanto cannot even credibly claim the documents are embarrassing, let alone prejudicial. Most importantly, this document is germane to Plaintiffs' PTO 8 argument that EPA's m ethodology and conclusions are fundamentally unsound in contrast with those of IARC. As such, the Court should reject

Monsanto's arguments that documents attached to Plaintiffs' PTO 8 Briefing are "irrelevant" or "tangential." Monsanto's argument that the documents are tangential is especially perplexing given the Court specifically requested the briefing submitted by Plaintiffs. *See* PTO No. 8.

In any event, the legal authority cited by Monsanto in support of these arguments is readily distinguishable as in those cases, the sealed documents were, in fact, tangential to the litigation. *See, e.g., Barnes v. Hershey Co.,* 2015 WL 1814293, at *2 (N.D. Cal. Apr. 21, 2015) (declining to seal certain documents and sealing documents containing confidential, trade secret information because the litigation was centered around an *employment* dispute). In fact, in *Hershey*, the court could find no "compelling reasons" to seal performance reviews and termination decisions as they were central to plaintiff's claims and because the "privacy interests were minimal and [] the public's interest in the disclosure of these documents for the legitimacy of the judicial process [was] heightened." *Id.*

Here, it is clear that Monsanto is opposed to making these documents public because some documents may be embarrassing or evidence company wrongdoing. However, as this Court has noted, that is not enough , and Monsanto is unable to cite a single case in which such a justification, without more, has been accepted by a court. See, January 27 , 2017 Transcript of Proceedings, 12:8 -13, **Ex. 1**. Rather, as in *Hershey*, documents related to flaws or bias in EPA methodology are central to Plaintiffs' allegations, and are certainly central to the Court's inquiry laid out in PTO 8; and therefore, are n ot properly shielded from public view. The public's interest in these documents is "heightened." As such, the Court should disregard Monsanto's arguments insofar as they allege Plaintiffs' documents attached to their PTO 8 Briefing are "irrelevant" or "tan gential.[2]" These documents are directly related, and necessary, to providing the response requested by the Court.[3]

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[2] The "tangential" analysis is not the proper analysis anyway, as the Parties have already stipulated to a de-designation challenge process. *See*, Joint Discovery letter filed on February 10, 2017 regarding the de-designation of "confidential" documents. Plaintiffs incorporate their portion of that joint letter as if fully set forth herein Dkt. 140.

[3] Defendants also argue the Court could simply strike Plaintiffs' exhibits. In support of this proposition, they cite a case in which the Court struck exhibits after finding the associated brief *moot*. Def.'s Resp. at 3 -4. Here, the Court *sua sponte* requested the PTO 8 briefing, so it is unlikely the Court will determine that the briefing is now

Finally, Monsanto's reliance upon *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 33 (1984) remains misplaced as the parties have negotiated and agreed to a Protective and Confidentiality Order. No matter how Monsanto attempts to make an end-run around this bargained for agreement, the Court should not allow Monsanto to continue abusing the Protective Order because they now have buyer's remorse. Here, the Protective Order "does not confer blanket protections on all disclosures or responses to discovery and [] ***the protection it affords from public disclosure and use extends only to the information or items that are entitled to confidential treatment under the applicable legal principles***" Protective and Confidentiality Order at ¶ 2 (emphasis added), Dkt. 64. In other words, the parties have already considered whether non-confidential information will be subject to public disclosure, and the Court ordered in the affirmative.

For these reasons, as explained more fully herein, Plaintiffs respectfully request that the Court deny Monsanto's request to keep documents attached to Plaintiffs' PTO 8 briefing under seal.

B. Monsanto Is Already Litigating The Case In The Court Of Public Opinion

A significant portion of Monsanto's brief argues "irreparable harm" if *non-confidential* documents are made public, and accuses Plaintiffs of engaging in 'trial by press.' In truth, it is Monsanto who is attempting to control the media and public opinion through its billion-dollar marketing/lobbying machine.

In response to a formal discovery request from Plaintiffs to Monsanto, Monsanto's attorney provided an incomplete list of website domains Monsanto owns or controls in the United States. **Ex. 2**.[4] Monsanto refused to provide any website domain maintained outside of the United States, even though

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moot; and therefore, the Court should disregard Monsanto's request to strike the documents. Moreover, Monsanto's additional cited case, *Mineba Co. Ltd. v. Papst*, 221 F.R.D. 11, 11-12 (D.D.C. 2004), is an example where the court had "previously expressed its frustration at the unnecessary volume of paper with which counsel feel compelled to inundated the Court." *Mineba*, 221 F.R.D. at 12. No such circumstances exist here.

[4] Plaintiffs have yet to receive a response from Monsanto itself. Monsanto designated this attorney letter as "Confidential" despite the fact the response is primarily a list of publicly accessible website domains, thereby forcing Plaintiffs to file the letter under seal and redact the names of public websites in this Reply. This is illustrative of the more general problem Plaintiffs are facing: Monsanto's continuing and unreasonable refusal to de-designate documents that are not confidential.

such websites can be accessed within the United States. *Id.* On February 15, 2017, undersigned counsel randomly selected the second website domain from the list entitled "monsantoblog.com" and viewed contents that were posted to the website after the first Roundup® case was filed on September 22, 2015. From that date forward, monsantoblog.com exemplifies the textbook definition of litigating a case in the press. The entries on monsantoblog.com attack the credibility of IARC's assessment, bolster EPA's conclusions (which, of course, are compromised by Monsanto's intentional efforts to inject biases and flaws into the agency's process), directly address "recent litigation," and accuse Plaintiffs' attorneys of solicitation. *See* **Ex. 3A**, "Here We Go Again: Dr. Oz and Glyphosate" dated September 24, 2015 (alleging "IARC took a very different approach and selectively included and interpreted data to classify glyphosate in Category 2A. The IARC classification conflicts with the overwhelming consensus of regulatory agencies . . . ."); **Ex. 3B**, "Addressing Recent Litigation on Glyphosate" dated October 8, 2015 ("after the classification of glyphosate by IARC in Category 2A in March 2015, plaintiffs' attorneys in the United States began soliciting plaintiff for potential lawsuits . . . we believe glyphosate is safe for human health when used as labeled and that this suit is without merit"); **Ex. 3C**, "Have You Heard That Glyphosate Causes Cancer" dated April 20, 2016 ("You may have heard that glyphosate causes cancer? You may have also heard recently that red meat causes cancer. If you have, it's because last year, a group called the International Agenc y for Research on Cancer (IARC), decided both are "probable" carcinogens."); **Ex. 3D**, "Monsanto's Continued Concerns About IARC Glyphosate Claims" dated May 12, 2016 ("Given the obvious flaws in its process, the IARC report has s purred much direct criticism from global regulatory agencies and scientific experts . . . ."); and **Ex. 3E**, "Monsanto Responds to Misleading New York Times GMO Article" dated October 31, 2016 ("despite the article's alarmist language about pesticide safety, it is important to note that all pesticides registered for use in the United States have undergone rigorous health and safety evaluations by the U.S. Environmental Protection Agency (EPA)." Several of these "blog posts" are demonstratively false and only serve to advance Monsanto's litigation position in the court of public opinion.

Exhibits 3A-3E are only a random sampling of blog entries from just one of the website domains owned or controlled by Monsanto out of an incomplete list of 36 websites. Further, each article contains numerous hyperlinks to other articles conveying a similar message, which then link to other similar articles, and so on, creating a labyrinth of disinformation. Additionally, Monsanto is a member of several industry organizations that use the media to prom ote their primary agenda: stopping these lawsuits and this MDL. One example is the American Chemistry Council, which launched the "Campaign for Accuracy in Public Health Research" ("CAPHR") a few weeks ago on January 25, 2017 (Monsanto is a member of the American Chemistry Council, although that membership is not apparent from CAPHR's website).[5] The launch of CAPHR was accompanied by considerable media coverage. Despite its name, CAPHR's primary purpose is to discredit IRAC and IARC's determination that glyphosate is a "probable carcinogen." Indeed, CAPHR's website currently claims it will seek reform of IARC because "IARC's Monographs Program suffers from persistent scientific and process deficiencies that result in public confusion and misinformed poli cy-making.[6]" The CAPHR's campaign to discredit IARC "will be supported by a news website and Twitter handle." *Id.*

Another example is CropLife, of which Monsanto is a primary and influential Member. On June 17, 2016, CropLife reported that it had:

> "taken a series of measures to align the industry on its approach to IARC, made numerous requests for meetings with WHO/IARC, mobilized the scientific community to question the role of IARC, and **encouraged increased reporting in the media** to balance the debate. Specifically, **CropLife International's outreach to media has sought to question the IARC classification process**, clarify their mandate (hazard v. risk) and expose conflicts of interest within IARC's secretariat and body of experts[7]." Emphasis Supplied. **Ex. 4**, Page 1, Executive Summary.

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[5] Monsanto's fingerprint is frequent but often hard to find. To that end, through formal discovery, Plaintiffs requested a complete list of consultants Monsanto paid for work related to Roundup®, glyphosate, and surfactants. Monsanto's attorneys refuse to provide that list.

[6] https://www.americanchemistry.com/Media/PressReleasesTranscripts/ACC-news-releases/ACC-Launches-Campaign-to-Promote-Credibility-in-Public-Health-Research.html, last visited February 16, 2017.

[7] Dr. Janet Collins is CropLife's Senior Vice President of Science and Regulatory Affairs. Prior to serving in that capacity, Dr. Collins was Monsanto's long tenured Director and Lead for Global Regulatory Organization. On August 24, 2016 and again on October 12, 2016, Dr. Collins wrote to the EPA to request that 'unfriendly' scientists be removed from the FIFRA SAP meeting. **Ex. 5A-5B**. Plaintiffs have issued a Third Party Subpoena to Dr. Collins, and are meeting and conferring with her attorney about her refusal to produce certain documents.

CropLife further described its ongoing global network strategy to 'challenge the credibility of IARC' by:

> "working with issue management consultancy v -Fluence to generate proactive news/commentary articles published in relevant/influential spaces…the second half of the strategy has involved intelligence sharing with a network of bloggers, commentators and journalists…"

Ex. 4, Page 2, "CropLife International Strategy."

On September 4, 2015, the California Office of Environmental Health Hazard Assessment (OEHHA) announced its intention to place glyphosate on California's Proposition 65 list. In response, Monsanto sued OEHHA and headed to the press. Indeed, as stated byMonsanto employee Sam Murphy on January 21, 2016, to "*amplify [its] message on the [Prop 65] lawsuit* ," Monsanto " *execute[ed] a proactive mainstream and social media effort.*" Emphasis Supplied, **Ex. 6.**

In sum, Monsanto has engaged a sophisticated campaign of misinformation meant to discredit Plaintiffs, Plaintiffs' attorneys, IARC, and other third parties that have opined on the carcinogenic nature of glyphosate.

C. Monsanto Has Not Demonstrated Good Cause or That Any Minimal Privacy Interest Outweighs The Public Interest In Viewing The Documents.

In the instant matter, Monsanto understates the public's interest in reviewing documents attached to Plaintiffs' PTO 8 briefing, while overstating the value of these documents as "proprietary" or "containing confidential strategies and business plans." The documents attached to Plaintiffs' PTO 8 briefing evidence Monsanto's intentional behavior aimed at obtaining a desired result from EPA, *i.e.*, the documents evidence Monsanto's intentional, and successful, attempts to bias and flaw EPA's methodologies. This constitutes, at best, embarrassing company conduct, but notwithstanding the embarrassment Monsanto may suffer, Monsanto does not cite a single case in which a court held that evidence of a company's intentional in terference with the proper functioning of a federal agency constitutes good cause for filing documents under seal.[8]

[8] *See, e.g., Brown & Williamson Tobacco Corp. v. F.T.C.*, 710 F.2d 1165, 1180-81 (6th Cir. 1983) (refusing to seal records as public had a "strong interest" in obtaining accurate health information related to the levels of tar and nicotine in cigarettes);*Nycomed US, Inc. v. Glenmark Generics, Inc*, 2010 WL 889799, at *6 (E.D.N.Y. Mar. 8, 2010) (refusing to seal documents containing allegations of wrongdoing even though party seeking protection

Monsanto's argument as to good cause is premised on its misunderstanding of the direct relevance of Plaintiff's filed documents, that is, Monsanto again argues the documents were filed "in support of a non-dispositive discovery motion that is at most tange ntial to this litigation." Def.'s Resp. at 8. First, it is clear that Plaintiffs' PTO 8 Briefing is not a "discovery motion;" but rather, a brief related to general causation submitted at the request of the Court. Thus, the documents attached to the same are not "tangential" but include information that is currently at the front and center of this litigation. These documents demonstrate that Monsanto has engaged in a longstanding effort to control the science as it relates to its products. These documents s how that Monsanto employees secretly infiltrated the peer - review boards of scientific journals to "reject" any article that was contrary to Monsanto's business interests. Other documents demonstrate Monsanto's unabashed use of ghostwriting to generate publications, written by Monsanto, but published under supposedly "independent" scientist's names, without any disclosure of Monsanto's involvement. Indeed, some of these documents reveal old fashioned bullying, whereby Monsanto discredits or attacks a scientist if they deign to publish anything unfavorable about glyphosate or Roundup. And all of these documents culminate to show that Monsanto improperly biased and injected flaws into EPA's methodology.

These gross deviations from basic decency warrant absolu tely no confidential protection, let alone this Court's departure from the principles of transparency that govern the judicial process. Assuming *arguendo*, Monsanto could demonstrate good cause to keep Plaintiffs' filed exhibits under seal, *i.e.*, Monsanto could show specific prejudice and harm from making these documents public, the Court still must "balance the public and private interests to decide whether [maintaining] a protective order is necessary." *Crossfit, Inc. v. Nat'l Strength & Conditioning Ass'n* , 2015 WL 12466532, at *4 (S.D. Cal. July 16, 2015). There is a strong public interest in getting these documents out from the veil of secrecy. Indeed, Monsanto is well aware of the need to get documents concerning its misconduct into

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alleged it would suffer competitive harm); and *Raytheon Aircraft Co. v. U.S.*, 2007 WL 4300221, at *9 (D. Kan. Dec. 8, 2007) (granting defendant's motion for a protective order because evidence of wrongdoing was absent and noting plaintiff could move to modify if evidence of wrongdoing was located).

the public domain. *In re Agent Orange Prod. Liab. Litig.*, 104 F.R.D. 559, 575 (E.D.N.Y. 1985), *aff'd, Agent Orange I*, 821 F.2d 139 (2d Cir. 1987).

The only other argument asserted by Monsanto in support of good cause is that courts have, at times, protected the privacy ri ghts of third parties, and that "[s]ome of the documents at issue contain information regarding exchanges with outside consultants or with other companies who are not parties to the dispute." Def.'s Resp. at 9. However, Monsanto makes no argument as to how the interests of these consultants or third parties may be impaired. In fact, as a general matter, the mere existence of a third party does not lead to the conclusion that a document must remain confidential and sealed. *Kamakana v. City and County of Honolulu*, 447 F.3d 1172, 1180 (9th Cir. 2006) ("a party must make a particularized showing with respect to any individual document in order to justify sealing the relevant document"). Thus, Monsanto's mere invocation of the words "consultants" and "companies" falls far short of the showing required to keep these documents under seal.

D. Monsanto Improperly Asks This Court To Adopt A Prejudicial Order That Will Negatively Affect Plaintiffs

The Court should deny Monsanto's improper, and prohibitively broad, request that the Court enter an Order prohibiting Plaintiffs from filing discovery documents as exhibits to motions or other filings regarding discovery or case management issuesunless requested by the Court ("Filing Prohibition Order"). See, Proposed Order, Dkt. 143-2. The sole motivation behind this request is Monsanto's wish to hide embarrassing documents from the public and litigate this case in complete secrecy. Not only is Monsanto's proposed Filing Prohibition Order oppressive, prejudicial, and unprecede nted, the interpretation of that request is ripe for conflict. For instance, how will the Court know when or what to "request" without reviewing the tens of millions of discovery documents and participating in ***all*** aspects of discovery? The answer is simpl e: it can't. To be clear, Plaintiffs do not dispute the need to keep confidential documents that are actually confidential, which is why Plaintiffs stipulated to a Protective Order in the first place. But Monsanto's request extends beyond the Protective Or der to infringe upon Plaintiffs' due process rights.

Further, Plaintiffs have found no case in which this drastic action was ordered absent prior warnings from a court regarding excessive filings. That is not the case here. Accordingly, Monsanto's further request can only be construed as an attempt to avoid its obligations under the Protective and Confidentiality Order, which requires the parties to engage in a specific process for de -designating documents that, after review, do not warrant treatment as confidential.

E. CONCLUSION

For the reasons stated above, Plaintiffs respectfully submit that the Court deny Monsanto's request to make permanent the sealing of the Exhibits attached to Plaintiffs' PTO 8 briefing. Plaintiffs further submit that the Court should deny Monsanto's reque st for an "order that discovery material not be filed as exhibits to any future discovery or case management filings unless requested by the Court" because it is an unreasonable restraint on the parties' due process rights.

Dated: February 17, 2017

/s/ Aimee Wagstaff, Michael Miller, Robin Greenwald

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ECF CERTIFICATION

Pursuant to Civil Local Rule 5-1(i)(3), the filing attorney attests that she has obtained concurrence regarding the filing of this document from the signatories to the document.

DATED: February 17, 2017

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was filed with the Court and electronically served through the CM-ECF system which will send a notification of such filing to all counsel of record.

DATED: February 17, 2017

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EXHIBIT 1

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

Before The Honorable Vince Chhabria, Judge

IN RE: ROUNDUP PRODUCTS LIABILITY LITIGATION

NO. 16-md-02741 VC

San Francisco, California
Friday, January 27, 2017

TRANSCRIPT OF PROCEEDINGS

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Also Present: **Jeffrey Messinger (via telephone)**
Heather Pigman (via telephone)
Dena Young (via telephone)

Friday - January 27, 2017 **10:05 a.m.**

P R O C E E D I N G S

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THE CLERK: Calling Case Number 16-md-2741, In Re: Roundup Products Liability Litigation.

Counsel, please state your appearances for the record.

MR. MILLER: Good morning, Your Honor. Michael Miller on behalf of plaintiffs.

THE COURT: Good morning.

MS. GREENWALD: Good morning, Your Honor. Robin Greenwald for plaintiffs.

THE COURT: Good morning.

MS. WAGSTAFF: Good morning, Your Honor. Aimee Wagstaff for the plaintiffs.

MR. HOLLINGSWORTH: Good morning, Your Honor. Joe Hollingsworth for Monsanto.

THE COURT: Good morning.

MR. SULLIVAN: James Sullivan for Monsanto.

THE COURT: Good morning.

Okay. Today you can talk as fast as you want and interrupt each other as much as you want because we have Jo Ann Bryce as our court reporter, and Jo Ann, if you want to read a little more about her, you can Google "Jo Ann Bryce" and *"Wall Street Journal."*

Okay. Let me sign onto my iPad here. Sorry.

You really should Google "Jo Ann Bryce" and *"Wall Street Journal."* It's an awesome article.

MS. GREENWALD: We will.

THE COURT: Okay. So it seems like we don't have that much to talk about today. On the -- we have some scheduling stuff. I want to talk a little bit about sealing, and we have the Common Benefit Fund.

I guess on the Common Benefit Fund, I don't really see -- I guess what struck me -- what jumped out at me is that it's not clear why we need to set a number now, and it strikes me that that number could be very different depending on how Phase I comes out. So why not wait until then and use Monsanto's language until then?

MS. WAGSTAFF: Your Honor, if I may. Aimee Wagstaff.

I think that one of the main reasons to set a number now is so that counsel who participate or want to file in this MDL know sort of what the financial obligations are for them and for their clients; and I think that it's -- the earlier that we can set a number, I think the better for that exact reason.

You know, for us and this counsel right here that has participated in the MDL, that may be okay to do, but there are other counsel all around the country that are waiting to see sort of what number is set or what the Court does with respect to the Common Benefit Order in terms of whether or not they want to participate in this or not.

THE COURT: But if the number is 4 percent or 6 percent or 3 percent or 7 percent, is that really going to affect anybody's decision whether to file a lawsuit?

MS. WAGSTAFF: It may. Well, 3 -- I mean, 3 percent and 4 percent maybe not; but it's not whether or not to file a lawsuit, but it may determine whether or not they go to State Court or Federal Court.

THE COURT: Okay.

MS. WAGSTAFF: And I think that that is -- you know, I think that the goal -- one of the goals, I think, of Your Honor and I think of sort of the MDL leadership is to keep this MDL as sort of the center of the universe as much as we can and as possible as we can.

THE COURT: But wouldn't a higher number -- well, why would a higher -- like, which way would it cut? If there's a higher number, they're more likely to go to which court?

MS. WAGSTAFF: Well, it depends. It depends on who you're talking about. And I think that 7 percent, which is a number that we proposed, is very in line with most of the MDLs that are around the country.

THE COURT: But if it's a higher or lower number, how does that affect which court somebody might want to go to?

MS. WAGSTAFF: If it's -- if you get into the double digits, I think -- so a lot higher, like 10, 11, 12 percent, which a lot of courts have done -- some people who are not

going to have an active role in litigating the case may stay away from the MDL.

THE COURT: Okay. But they know you're asking for 7 percent.

MS. WAGSTAFF: Yeah. Well, we put it on the record.

THE COURT: So we're going to just adopt Monsanto's language and we can revisit it after Phase I.

MS. WAGSTAFF: Okay.

THE COURT: Okay. So there is -- let's talk about sealing for a second. There's a motion to seal portions of the case management statement and portions of Exhibit A to the case management statement. There hasn't exactly been an opposition -- or, sorry, there hasn't exactly been a declaration in support of that from Monsanto, just a statement that "We want to wait the 30 days -- you know, the standard 30-day period."

And then the other motion to seal we have is a motion to seal some aspects of the motion to compel the Rowland deposition, the EPA official, or former EPA official; and motion to seal some exhibits to the motion to compel the Rowland deposition, and that is largely e-mail communications, internal Monsanto e-mail communications, about Rowland and about Monsanto's communications with Rowland and sort of Monsanto's strategies for how to deal with the EPA and the federal government.

Overall what I will say is that you will find, if you go back and look at my history of ruling on motions to seal, that I probably deny 95 percent of motions to seal. Most motions to seal are frivolous and I deny them.

And the parties, particularly companies, take a completely unreasonable view on what should be confidential and what material would cause them competitive harm. And so I just want to say at the outset, if I see a pattern of frivolous motions to seal, I will start sanctioning people. I'll start sanctioning parties and I will start sanctioning lawyers.

This is a big case. There's going to be a lot of material, and I don't want to see a bunch of frivolous motions to seal.

With respect to the motion to seal the portions of the case management statement and portions of Exhibit A to the case management statement, I cannot possibly imagine an argument in support of sealing that material. If you want to make one now, go ahead, otherwise I'll deny that motion to seal right now.

MR. HOLLINGSWORTH: Your Honor, I wanted to make an argument about the Rowland documents.

THE COURT: Right now I'm talking about the case management statement and the Exhibit A to the case management statement.

MR. HOLLINGSWORTH: Okay. That goes to the objections?

THE COURT: Yes.

MR. HOLLINGSWORTH: Yes.

THE COURT: The deposition testimony.

(Pause in proceedings.)

MR. HOLLINGSWORTH: Well, Your Honor, the objections to the deposition testimony were made in connection with a motion to seal the entire transcript, and the motion to seal the entire transcript was --

THE COURT: Wait a minute. What?

MR. HOLLINGSWORTH: -- what --

THE COURT: I'm sorry. I don't understand. The objections --

MR. HOLLINGSWORTH: Maybe I'm confused, but the case management statement has some questions and answers and objections and colloquy.

THE COURT: From deposition testimony.

MR. HOLLINGSWORTH: Yes.

THE COURT: Correct.

MR. HOLLINGSWORTH: That --

THE COURT: And also Exhibit A to the case management statement has excerpts from deposition testimony that is proposed that is right now redacted.

MR. HOLLINGSWORTH: Yes.

THE COURT: Yes.

MR. HOLLINGSWORTH: I'm referring to the -- I'm

referring to the deposition of Dr. Farmer.

THE COURT: Right.

MR. HOLLINGSWORTH: Yes. We, to be safe because we had designated the entire transcript --

THE COURT: I understand. I read --

MR. HOLLINGSWORTH: Okay.

THE COURT: -- your statement about it in the case management statement --

MR. HOLLINGSWORTH: Yes.

THE COURT: -- that to be safe you designated the entire transcript confidential.

MR. HOLLINGSWORTH: Yes.

THE COURT: Right now what I'm asking is: Do you have any argument for why anything in the case management statement or Exhibit A to the case management statement should be under seal?

MR. HOLLINGSWORTH: Well, we did, Your Honor, and we made that argument. I hear Your Honor's statement and I heard Your Honor's statement that you have denied 95 percent of your motions to seal.

THE COURT: Okay. What's your argument for why any of this stuff in the case management statement or Exhibit A to the case management statement should be under seal right now?

MR. HOLLINGSWORTH: In light of Your Honor's comments, it's this: We designated the transcript as confidential in

accordance with Your Honor's order as we understood it in connection with protective orders and in accordance with the Federal Rules of Civil Procedure, especially Rule 30(c), and we thought that we would have 30 days to look at that transcript after we had received it --

THE COURT: Okay. But --

MR. HOLLINGSWORTH: -- at which time --

THE COURT: -- you have surely looked at the contents of -- you can take 30 days to look at the deposition transcript. You have surely looked at the case management statement and Exhibit A to the case management statement. Do you have any argument for why any of the redacted material in the case management statement or Exhibit A to the case management statement should be under seal?

MR. HOLLINGSWORTH: Well, that it's part of a transcript that we designated as under seal at this point, and the 30 days hasn't --

THE COURT: What do you mean "designated as under seal"? You designated it as confidential.

MR. HOLLINGSWORTH: That's right. Excuse me.

THE COURT: And the parties' decision to designate something as confidential bears no relationship at all to whether something should be filed under seal.

MR. HOLLINGSWORTH: Yes.

THE COURT: Now, portions of the transcript that

you've designated confidential have now been filed, and so I'm asking you, because your decision to designate something as confidential does not in any way support an argument to seal it, tell me, if you have any substantive reason, why any of the material in the case management statement or Exhibit A should be under seal.

MR. HOLLINGSWORTH: It's part of a transcript that we had designated as confidential, and we haven't gotten to the issue yet of what we would -- what we would attempt to have sealed or continue to have sealed, and we think it should remain confidential pending that sealing.

THE COURT: Okay. That's not the way to think about sealing. Anytime something is filed under seal -- so anytime the parties consider filing something under seal or discuss filing something under seal, the fact that something has been designated confidential is not a reason to file it under seal. You need to file a declaration to support filing something under seal.

I hate it when things are filed under seal that don't need to be filed under seal. It creates a lot of work for us. We have to go through and figure out whether there's any justification for sealing it. So you need to avoid at all costs filing anything under seal that does not justify filing under seal.

The motion to file the portions of this case management

statement and Exhibit A to the case management under seal is denied. So the parties will file an unredacted version of that by the close of business today.

MR. MILLER: Yes, Your Honor.

THE COURT: Regarding the motion to seal the materials connected to the Rowland deposition, I've reviewed them. It is very difficult for me to imagine a justification for sealing any of those materials; however, I will -- and I will say that often a company will file a motion to seal materials because the company perceives the material as embarrassing. I do not believe in the vast majority of cases that it is appropriate to seal material merely because it might be embarrassing to the company.

So I have a very difficult time imagining that I would grant a motion to seal any of the material submitted in connection with the motion to compel the Rowland deposition, but I will consider that as I consider the substance of the motion to compel the Rowland deposition and I will rule on it perhaps shortly before I rule on the substance of the motion to compel or in conjunction with the ruling on the motion to compel.

With respect to that, I signed a stipulation that would -- a stipulation was submitted to have a hearing on the motion to compel the Rowland deposition on the 22nd of February, which was going to be the same day as the case management conference,

and then there's a request to move the case management conference to March 8th.

Fine to move the case management conference to March 8th. So we'll go ahead and do that, but I do still want to hear the motion to compel the Rowland deposition before March 8th. So what I was going to propose, though, is that we hear that on February 27th.

MR. MILLER: That's fine, Your Honor.

THE COURT: Okay. So the motion to compel the Rowland deposition will be heard on the 27th.

And, by the way, I will decide the motion to quash the Texas A & M subpoena or the motion to quash the subpoena by Texas A & M in conjunction with deciding the motion to compel the Rowland deposition. As you saw from my order the other day, I think this is -- you know, there's kind of a global issue to think about, and I've asked for briefing on that issue, and I'll decide both the motion to quash the Texas A & M subpoena and the motion to compel the Rowland deposition together.

I don't need to hear further argument on the Texas A & M subpoena, but I will hold off on deciding it until we have our hearing on the Rowland deposition, which will be on the 27th.

And I would also like, and we'll figure out what time in a second, but I would also like to have science day on the 27th because it struck me that, you know, science day could have a

relationship to the Rowland -- you know, the question of how much discovery should be allowed relating to whether the EPA's conclusions about glyphosate were biased or flawed and whether the IARC's conclusions about glyphosate were biased or flawed. So would that work to have science day on February 27th?

MR. MILLER: From our perspective, that works.

MR. HOLLINGSWORTH: We think so, Your Honor. We need to check with some experts.

THE COURT: Okay. So why don't we schedule that for the 27th for now.

MS. WAGSTAFF: Your Honor?

THE COURT: Yeah.

MS. WAGSTAFF: With respect to science day, at the last conference that we were here with you, there was some -- there was an agenda item with respect to the scope of science day, and so that was sort of punted because science day was punted. Can we -- we aren't prepared, I think both parties, to discuss that today. Can we get that on a teleconference with you, or something, just so we know how to prepare for science day?

THE COURT: Sure.

MS. WAGSTAFF: Okay.

THE COURT: The overall guidance that I will give you, though, is that I do not want to hear any discussion of which studies are good studies, which studies are bad studies on this

issue. I want to learn about how to learn about it. Does that make sense?

Or, I guess, to put it another way, I want you to -- the purpose of science day is to try to give me the tools to be able to examine those studies and examine the expert testimony about those studies, but not to discuss the studies themselves.

So, in other words, it's more like a college course -- or for me you should probably treat it more like a high school course -- just on the general topic of I assume epidemiology and whatever other fields are relevant to examining these studies. Does that make sense?

MS. WAGSTAFF: Yeah.

THE COURT: Okay.

MR. HOLLINGSWORTH: Yes, Your Honor.

MS. WAGSTAFF: Thank you.

THE COURT: So I guess what I wouldn't mind doing is having science day first in the morning and then argument on the Rowland deposition in the afternoon, which I think could be helpful probably for the EPA lawyers. Coming out from D.C., it might be better for them to have it in the afternoon.

So science day 9:30. Plan on going till lunch. If we need to go longer, we can go longer. And we'll do argument on the Rowland -- motion to compel the Rowland deposition at, say, 2:00 o'clock.

Depositions -- oh, yeah. And then you wanted to sort of

calendar February 24th for a possible telephonic argument over any -- what was that argument going to be about? Any further depositions?

MR. MILLER: No. I think we're trying to work that out. We have a schedule that Your Honor set. I think what Ms. Wagstaff was talking about, there may be some debate about protocol on science day; wasn't it?

MS. WAGSTAFF: Yeah. But I think what you're talking about is the letter that we sent. So we have Group A -- or Group E, I'm sorry, that we have to designate on the 1st. And we've been pretty good about sort of narrowing down any disagreements, but we're going to have custodial files from particular I think Group D and then E after the people that we get custodial files. So we just want to make sure that we can -- if we have any, that we can get on the phone with you and you can sort of tell us which way to go.

THE COURT: Uh-huh.

MS. WAGSTAFF: And if we have it all ironed out and worked out, then we'll just cancel that with you.

THE COURT: That sounds fine. I'll sign that. And you already have a stip, I think.

MS. WAGSTAFF: We have a stip, but did we -- yeah, we submitted a stipulation with you too, and it said there the time for the teleconference to be determined by you. So if you could just add a time for that, we'll join it.

THE COURT: Okay. I will do it.

But I want to reemphasize, I said it several times, but I want to reemphasize that if you -- you know, on the issue of, you know, adding custodians, taking people's depositions, if there's disagreement, the plaintiffs have to make a detailed written showing in advance of why it's relevant and not duplicative.

MS. WAGSTAFF: Yeah. We hear you.

THE COURT: Okay. I don't think I can say it too many times.

So I think what remains, then, is the dispute about the depositions, and my -- I've reviewed the soon-to-be-unsealed excerpts of the deposition exchanges that are contained in the case management statement and Exhibit A to the case management statement, and my reaction is that Monsanto's conduct in those depositions is not unreasonable or overboard. And in light of that, I'm not prepared to impose the restriction that you're requesting.

You know, if Monsanto starts making speaking objections that are more detailed or with greater frequency such that you think you need to come back to me, I'll look at it again. And if Monsanto does go overboard, I will impose the restriction that you are requesting; but the objections that you included in the case management statement did not seem unreasonable to me.

MR. MILLER: Fine, Your Honor. Thank you.

THE COURT: Anything else for us to discuss today?

MR. MILLER: I think we have a lot of work to do, but I don't think there's anything left to discuss, Your Honor, honestly.

MR. HOLLINGSWORTH: Your Honor, on February 27th we'll do the best we can to make that date. As I said, we do have to talk to some of our experts.

I think February 27th possibly was a date that we suggested before, and we had -- we were under the impression that Your Honor was going to put science day off longer than February -- I was probably wrong about that -- so we released everyone.

THE COURT: Yeah. Yeah. No. No. I apologize. No, you were right about that and I changed my mind about it because I sort of came to the realization that, you know, in dealing with some of these discovery issues and in particular, you know, the IARC -- the question that I posed in my order the other day about the relevance of IARC bias and EPA bias, it made me realize that science day actually may be helpful in answering those questions. So that's why I changed track on you, and I apologize for that.

MR. HOLLINGSWORTH: So, therefore, can we inform the Court within two or three business days that February 27th is okay? I notice that the plaintiffs said it's definitely okay

with them. I think it will be okay with us. And if we've released people who can't come on the 27th, we'll try our best to find other people. So we're going to try real hard for the 27th.

THE COURT: Okay. Yeah. And, you know, again, keeping in mind it doesn't have to be, you know, your experts who are testifying on which studies are good and which studies are bad.

MR. HOLLINGSWORTH: Right.

THE COURT: It just needs somebody who can sort of teach me how to think about studies.

MR. HOLLINGSWORTH: Right. Thanks for your comments on that.

THE COURT: All right. Anything else?

MR. MILLER: No, Your Honor. Not from plaintiffs. I don't think so.

MR. HOLLINGSWORTH: No, Your Honor.

THE COURT: All right. Thanks very much.

MR. HOLLINGSWORTH: Thank you.

MS. GREENWALD: Thank you, Your Honor.

MR. MILLER: Thank you, Your Honor.

(Proceedings adjourned at 10:30 a.m.)

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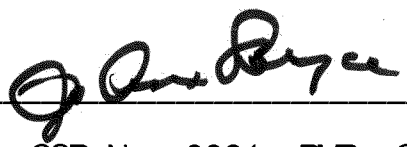
CERTIFICATE OF REPORTER

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

DATE: Friday, February 3, 2017



Jo Ann Bryce, CSR No. 3321, RMR, CRR, FCRR
U.S. Court Reporter

EXHIBIT 2

September 30, 2016

Hollingsworth LLP

Via Electronic Mail

Aimee H. Wagstaff, Esq.
Andrus Wagstaff, PC
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Lakewood, CO 80226

Rosemary Stewart
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CONFIDENTIAL; SUBJECT TO PROTECTIVE ORDER

Per your request, Defendant Monsanto Company ("Monsanto") has conducted a search for website domains it owns or controls. No such master list could be identified and, therefore, the below list was compiled for purposes of this litigation. Because different groups within Monsanto may own or control additional website domains, and due to the difficulty and expenditure of resources necessary to create this list, Monsanto cannot guarantee the completeness of this list and reserves the right to supplement or amend this list. Further, because plaintiff does not allege exposure to Roundup and/or glyphosate outside the United States, and due to the difficulty and burden that would be involved, the following list focuses on website domains for the United States. Monsanto also has not included website domains that it concluded do not address glyphosate or glyphosate-containing products. Further, the limited discussion of glyphosate or glyphosate-containing products on many of these sites appears to be cumulative or duplicative of previous productions from monsanto.com, monsantoblog.com, and discover.monsanto.com. In addition to the below list, while Monsanto does not own the website domain and does not concede control of the domain, Monsanto has contributed to the site gmoanswers.com from which Monsanto also has produced records in this litigation.

Website Domains: monsanto.com; monsantoblog.com; monsantoito.com; discover.monsanto.com; monsantohawaii.com; acceleronsas.com; aganytime.com; agseedselect.com; americasfarmers.com; corn-states.com; dekalb100yearsbook.com; fontanelle.com; genuity.com; goldcountryseed.com; hubnerseed.com; insectforecast.com; jungseedgenetics.com; krugerseed.com; lewishybrids.com; monsantoesolution.com; monsantoesolutions.com; monsantofund.org; npeedge.com; pre-serve.org; rea-hybrids.com; rounduppromax.com; roundupquikpro.com; roundupreadyplus.com; seminis.com; seminis-us.com; soybeans.com; specialtyhybrids.com; stoneseed.com; vistivegold.com; weedtool.com; channel.com

This disclosure does not concede relevancy or admissibility for any listed website domain or content therein.

Sincerely,

Rosemary Stewart

Rosemary Stewart
HOLLINGSWORTH LLP
Counsel to Defendant Monsanto Company

EXHIBIT 3

EXHIBIT 3 A

HERE WE GO AGAIN: DR. OZ AND GLYPHOSATE

We just watched the latest episode of Dr. Oz, and sadly, we weren't surprised by what we saw. Just like he did back in April, Dr. Oz used the IARC classification of glyphosate in Category 2A to raise confusion and concern with his viewers.

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AUTHOR

Wes Matthews

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As a company, we're eager for folks to know more about how our products help farmers produce food in a more environmentally sustainable way. We want folks to know that we take safety extremely seriously, and glyphosate has undergone rigorous safety evaluations by regulatory agencies around the

world. Unfortunately, experience has shown us that with its current approach, the Dr. Oz program isn't the right place for these kinds of detailed and science-based discussions.

In fact, the Dr. Oz program didn't even reach out to us prior to filming this segment. When we heard Dr. Oz was having another discussion about glyphosate, we reached out to offer background information and our perspective so that viewers could decide for themselves. We'd like to share our point of view here as well.

Dr. Oz attempted to argue that the use of pesticides like glyphosate on herbicide-tolerant crops is a reason foods derived from GM crops should carry special labels. We strongly disagree with this argument as well. The use of chemical crop protection products is not limited to GM crops. However, regardless of whether crop protection products will be used on GM or conventional crops, the products undergo detailed regulatory reviews for safety.

Glyphosate-based herbicides have a 40-year history of safe use. This is backed up by more than 800 studies on glyphosate safety, many conducted by independent researchers. Regulatory agencies and scientific organizations, like the U.S. EPA, Health Canada and others, have reviewed all the key studies considered by IARC – and more – and arrived at the conclusion that glyphosate can be used safely when label instructions are followed. Numerous long-term studies of glyphosate have concluded that glyphosate does not pose a cancer risk in humans.

In contrast, IARC took a very different approach and selectively included and interpreted data to classify glyphosate in Category 2A. The IARC classification conflicts with the overwhelming consensus of regulatory agencies around the world and the findings of thee other WHO programs that have reviewed glyphosate safety.

We welcome your questions about glyphosate, GM crops or any

topic related to our business. Feel free to share what's on your mind at discover.monsanto.com. You can also learn more about glyphosate at Monsanto.com/glyphosate or GMOAnswers.com.

External sources on Glyphosate safety

Peer-reviewed scientific publications

- Regulatory Toxicology and Pharmacology. 31: 117-165. Gary M. Williams, Robert Kroes and Ian C. Munro (2000). Click here for a summary of the Williams' review.
- Reviews of Environmental Contamination and Toxicology. 167: 35-120. John P. Giesy, Stuart Dobson and Keith R. Solomon (2000).Click here for a summary of the Giesy review.
- An extensive collection of glyphosate-related publications is available here.

U.S. Environmental Protection Agency (EPA) review documents

- EPA Reregistration Eligibility Decision– Fact Sheet
- EPA, September 1993 / Full dossier

Worldwide governmental review documents

- Europe
- Commission working document– Review report for the active substance glyphosate / Finalized in the Standing Committee on Plant Health (June 2001)
- Germany
- Current, preliminary assessment of glyphosate by the BfR (July 2011)

Frequently Asked Questions on the Health Risk Assessment of Glyphosate (November 2011)

- FranceAFSSA-Statementon the substance glyphosate (add date)
- AustriaStatement about a study on toxicological effects of glyphosateBenachour N. and Seralini G.-E. (2009)

Information of the Austrian Agency for Health and Food Safety (AGES) on glyphosate

- AustraliaReview of the National Registration Authority(add date)

Report of the Australian Pesticides and Veterinary Medicines Authority (APVMA) of the Earth Open Source study "Roundup and birth defects: Is the public being kept in the dark?"
Regulatory update: APVMA sees no need to revise the current Australian Acceptable Daily Intake (ADI).
World Health Organization (WHO) review documents

- WHO environmental health criteria of glyphosate (1994)
- Joint FAO/WHO evaluation (2004 Part II—Toxicology) with information on the acceptable daily intake of glyphosate (ADI)
- WHO Drinking Water Guidelines for glyphosate and AMPA

Other review documents
A glyphosate summary is available online at EXTOXNET, a cooperative effort of University of California-Davis, Oregon State University, Michigan State University, Cornell University and the University of Idaho.http://ace.ace.orst.edu/info/extoxnet/pips/ghindex.html

EXHIBIT 3 B

ADDRESSING RECENT LITIGATION ON GLYPHOSATE

Glyphosate-based herbicides have a 40-year history of safe use. Glyphosate has been the subject of more than 800 different health and safety studies, and no regulatory agency in the world considers glyphosate to be a carcinogen. However, after the classification of glyphosate by IARC in Category 2A in March 2015, plaintiffs' attorneys in the United States began soliciting plaintiffs for potential lawsuits. These attorneys are attempting to tie the IARC classification to individual cases of cancer, and they're running ads to recruit plaintiffs in local newspapers and on the radio. At this time, one individual lawsuit is pending.

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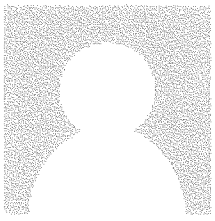
Tags: human health, IARC, Safety Studies

AUTHOR



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While we're sympathetic to individuals experiencing health problems, including those alleged by the plaintiffs in this case, we believe that glyphosate is safe for human health when used as labeled and that this suit is without merit. Decades of experience within agriculture and regulatory reviews using the most extensive worldwide human health databases ever compiled on an agricultural product contradict the claims in the suit which will be vigorously defended.

A number of resources are available to answer questions about glyphosate and its history of safe use. We invite you to review the resources below. If you don't see find an answer to your question, feel free to ask us at discover.monsanto.com.

EXHIBIT 3 C

HAVE YOU HEARD THAT GLYPHOSATE CAUSES CANCER?

By Robb Fraley, Executive Vice President & Chief Technology Officer

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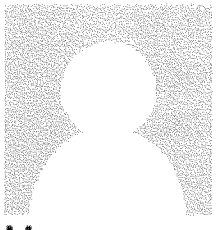
AUTHOR



M.

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Have you heard that glyphosate causes cancer?
You may have also heard recently that red meat causes cancer. If you have, it's because last year, a group called the International Agency for Research on Cancer (IARC), decided both are "probable" carcinogens. Coming from a group with ties to the World Health Organization, the attention – and, unfortunately, the

found that at least 61 of those scientists served on monograph working groups that considered their own scientific research."

I encourage anyone with concerns about glyphosate safety to read the Reuters special report and consider that IARC's classification is inconsistent with the overwhelming consensus of regulatory authorities around the world, who have assessed all the studies examined by IARC – and many more.

Indeed, while IARC's erroneous classification of glyphosate has attracted media attention and been used repeatedly as a scare tactic by activists, regulators around the world continue to support the safe use of glyphosate. In just the 13 months since IARC classified glyphosate, regulatory authorities in Europe, Canada, Japan and Australia have publicly reaffirmed that glyphosate does not cause cancer.

Unfortunately, much of this important context has been missing from the media coverage around IARC's classification of glyphosate, which is a shame because IARC reports not only create unnecessary confusion with consumers, but they also fuel efforts by activist groups to mislead the public with shoddy science.

In late May, IARC will convene again – this time to evaluate the potential carcinogenic risks of coffee and other hot beverages. Hopefully this time around there will be more conversation about what an IARC classification really means.

"If I say the world is round and someone else says it's flat, that's worth reporting. But you might also want to report on a bunch of scientific evidence that seems to support the notion that the world is round." – President Obama

EXHIBIT 3 D

MONSANTO'S CONTINUED CONCERNS ABOUT IARC GLYPHOSATE CLAIMS

By Scott Partridge, Monsanto Vice President Global Strategy

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Tags: cancer, Glyphosate, IARC, Monsanto, RoundUp

AUTHOR

Nick Weber

More →

At Monsanto, I work with many teams that research and develop products to help farmers, and ultimately, consumers, every day. These teams rely on the science to guide their decision-making, and they adhere to the rigorous regulatory processes established by governments around the world to bring our products to market. Recently, glyphosate, the main ingredient in Monsanto's Roundup agricultural herbicides, has been under attack by a French-based group called the International Agency for Research on Cancer (IARC). Its activities have raised a lot of questions, which we

intend to explore further.

A 40-Year History of Safe Use

Glyphosate has been called the most important herbicide developed in the post- World War II era. For over 40 years, the EPA – and all other regulatory and scientific agencies worldwide who have reviewed glyphosate – have concluded that glyphosate does not pose a cancer risk to humans. Many of these reviews were completed in the last few months. In April 2015, the Canadian Pest Management Regulatory Authority concluded that "glyphosate is unlikely to pose a human cancer risk." In November 2015, the European Food Safety Authority concluded that "glyphosate is unlikely to pose a carcinogenic hazard to humans." And in March 2016, the Food Safety Commission of Japan concluded, "No neurotoxicity, carcinogenicity, reproductive effect, teratogenicity or genotoxicity was observed."

IARC's Flawed Report, and Reactions from Scientists and Regulators

In March 2015, a non-governmental French-based group called the International Agency for Research on Cancer ("IARC") reported that it had performed its own review of some glyphosate literature. During its one-week review process, the group, by its own admission, ignored much of the vast content and numerous studies used by governmental regulatory agencies and scientists over the past four decades to rigorously assess the safety of glyphosate. Instead, the IARC group selected a subset of information for review, including reports that were self-authored by IARC's own members, and studies that had been soundly discredited by other scientists. Following IARC's abbreviated and subjective review of a portion of the literature, the group reached a flawed conclusion, claiming glyphosate is "a probable carcinogen." Members of the IARC panel then mounted an aggressive publicity and lobbying campaign to convince others, even though their conclusion contradicted the findings of all the

other scientists and global regulatory agencies that have addressed the issue, including three other entities within the World Health Organization.

Given the obvious flaws in its process, the IARC report has spurred much direct criticism from global regulatory agencies and scientific experts, who have confirmed that the scientific evidence does not support IARC's conclusions; and other prominent scientists have claimed IARC even misrepresented their work altogether. For example, the German Rapporteur Member State for the glyphosate re-evaluation in the EU discredited the IARC claims in a 122 page, study-by-study assessment of the IARC work, and concluded "the weight of evidence suggests that there is no carcinogenic risk related to the intended herbicidal uses and, in addition no hazard classification for carcinogenicity is warranted for glyphosate according to the CLP criteria." And Dr. Keith Solomon, a renowned scientist in this area that was cited by IARC, left no doubt about their misuse of his work, stating, "They (IARC) got this totally wrong. They said the study showed there was a relationship.... It's certainly a different conclusion than the one we came to."

EPA's Cancer Assessment Review Committee Report

Most recently, the EPA added its weight to the debate, with an 87-page "Final Report" from the EPA's own Cancer Assessment Review Committee ("CARC") on April 29, 2016. The EPA's scientists thoroughly reviewed the mutagenicity studies, toxicology studies and epidemiology studies (including, among others, the Department of Health and Human Service's large, prospective Agricultural Health Study), with a particular focus on those studies that IARC found persuasive. The EPA specifically addressed and rejected each of the lines of evidence used by IARC, and reaffirmed the safety of glyphosate. The EPA's Final Report, like those from other agencies around the world, used sound science and a rigorous process to set the record straight

on the safety of glyphosate.

Questions about IARC and the harm it is causing to public policy

The controversial IARC claims continue to create unfounded confusion, public fear, and wasted resources. In large part, this is due to the aggressive publicity and lobbying campaign initiated by IARC scientists, who are trying to convince regulators to replace the body of well-established science with IARC's flawed findings and biased perspectives. This is creating needlessly misinformed debate, undermining public policy, and harming affected industries that depend on thorough and accurate scientific assessments.

The publications and tactics of IARC and its members about glyphosate raise many serious questions about their purposes and processes. And while pretending to operate under a banner of science, they abuse and ultimately undermine the fundamental public trust placed in our scientific institutions. Given the importance of these issues to the public, to farmers, to our industry, and to the thousands of real scientists and public health officials working hard every day to fulfill their mission, we intend to find answers to the numerous questions surrounding IARC… and we will share what we learn. But from what we've seen thus far, the IARC efforts have little to do with science or public health.

It is my hope that sound science and rigorous regulatory processes will continue to guide our public health debates and policies.

Originally published May 12, 2016 by Nick Weber

EXHIBIT 3 E

MONSANTO RESPONDS TO MISLEADING NEW YORK TIMES GMO ARTICLE

We were disappointed to read this weekend's piece on GMO crops in the New York Times ("Doubts About the Promised Bounty of Genetically Modified Crops"). The reporter chose to cherry-pick data to argue that GMOs have failed to provide significant benefits, especially yield increases, to farmers in the United States. The reporter's arguments were misinformed– and overlooked the perspectives of millions of farmers in the United States, India, South America and elsewhere in the world, who have chosen to plant GMOs over the past two decades.

1.4K

Tags: GMO benefits, GMOs, New York Times
AUTHOR

Nick Weber
More →

We were especially disappointed because we engaged with this reporter on multiple occasions over several months to provide interviews, background information and recommendations of third-party experts and resources. Much of this context was omitted from the article. As a result, the article may create unfortunate confusion and concern among consumers who are unfamiliar with modern agricultural practices.

As we told the reporter on multiple occasions, analyzing yield trends across geographies is complex because agronomic characteristics, maturity rates and other factors have to be taken into consideration. Making comparisons across very broad geographies – such as the United States and Europe – is especially difficult. Focusing on a comparison between smaller regions allows for better control of those variables and a more accurate comparison.

For instance, in a new analysis on the Huffington Post, Monsanto's Chief Technology Officer, Dr. Robb Fraley, analyzes yield trends between the Canadian province of Ontario and the country of France. These two regions are agronomically similar. The big difference? GMOs are common in Ontario but not used in France. From 1997 to 2015, corn yields increased in Ontario by 51 percent, while French yields only grew about 10.5 percent.

Importantly, while this increase is significant, yield improvement is only one of the many benefits GMOs offer to modern agriculture. Let's look more broadly at those benefits.

The article completely overlooked the benefits of GMOs for farmers in the developing world – an area where this new technology is truly changing lives, particularly when it comes to food security. According to Qaim and Kouser (2013), access to insect-resistant GMO cotton in India has increased family incomes and improved calorie consumption significantly. Indeed, because of access to GMOs, food insecurity among Indian cotton-producing households has fallen by 15 to 20 percent.

GMOs and other modern agricultural tools have also helped accelerate the adoption of practices such as conservation tillage and no-till, which helps increase carbon sequestration in soil. Brookes and Barfoot (2016) calculated that in 2014 alone, conservation tillage enabled by glyphosate-tolerant GMO corn and soybean removed 22.4 billion kilograms of carbon dioxide from the atmosphere. That's the equivalent of taking 10 million cars off the road for a year. That benefit alone should make headlines.

The article also made misleading claims regarding the use of pesticides on GMOs. Brookes and Barfoot also report that GMOs have reduced pesticide spraying from 1996 to 2015 by 8.2 percent.

In addition, despite the article's alarmist language about pesticide safety, it is important to note that all pesticides registered for use in the United States have undergone rigorous health and safety evaluations by the U.S. Environmental Protection Agency (EPA). These assessments ensure that pesticides can be used safely according to their label instructions, whether they are being used on GMOs, conventional or organic crops.

It's easy for anyone to cherry-pick numbers to make a misleading argument. But it's impossible to argue with the real-world benefits both large and smallholder farmers have seen around the world. As a company, we are committed to delivering new tools and innovations to growers to help nourish our world in a more

sustainable way. We believe GMOs are one important tool, among many, that will help feed our growing world. We invite readers of the Times piece to dig deeper than the headlines and explore the benefits of GMOs for themselves. A great place to start is at discover.monsanto.com or GMOAnswers.com. Here's a running list of links to responses by farmers, academics and others who are providing accurate information and setting the record straight on misinformation in the article as well.

EXHIBIT 4

CropLife INTERNATIONAL

MEETING PRE-READ

Agenda Item:	13c
Prepared by:	W. Surman
Date:	17 June 2016
Reviewed by:	H. Minigh
Status:	DRAFT
To:	Plant Biotech Strategy Council

Title: **IARC – Recent Developments and Industry Actions**

Executive Summary:

The IARC classification linking several pesticides to human carcinogenicity has caused widespread media attention and continued calls on national regulators and retailers to ban the sale and use of crop protection products deemed probable carcinogens by IARC. There has been particular focus on the active substance glyphosate. Recently the WHO/FAO Joint Meeting on Pesticide Residues (JMPR) concluded glyphosate, diazinon and malathion are "unlikely to pose a carcinogenic risk to humans from exposure through the diet" in contrast to the 2015 assessment from IARC, which classified each of these compounds as a "probable" cause of cancer.

CropLife International has taken a series of measures to align the industry on its approach to IARC, made numerous requests for meetings with WHO/IARC, mobilized the scientific community to question the role of IARC, and encouraged increased reporting in the media to balance the debate. Specifically, CropLife International's outreach to media has sought to question the IARC classification process, clarify their mandate (hazard vs risk) and expose conflicts of interest within IARC's secretariat and body of experts.

The PBSC is requested to take note of the strategy and latest developments.

Background:

The [HYPERLINK "http://www.iarc.fr/en/media-centre/pr/index.php"] (IARC) is the specialized cancer agency of the World Health Organization (WHO). Its objective is to promote international collaboration in cancer research and to bring experts together to identify the causes of cancer so that preventive measures may be adopted. In April 2014 an IARC Advisory Group met to recommend topics for assessment in 2015–19 and pesticides were identified as a "high priority". [HYPERLINK "http://monographs.iarc.fr/ENG/Publications/internrep/14-002.pdf"] is a full list of crop protection products identified by IARC for review between 2015 and 2019. The list includes Genetically Modified Organisms (GMOs).

The first meeting on pesticides was held in March 2015 when the IARC panel classified glyphosate and malathion to be "probably" carcinogenic to humans and parathion, and diazinon and tetrachlorvinphos to be "possibly" carcinogenic to humans. The second meeting on pesticides was held in June 2015 when the IARC panel classified DDT to be "probably" carcinogenic to humans, 2,4-D as "possibly" carcinogenic to humans and lindane as "carcinogenic to humans". In July 2015 IARC published the Monograph on glyphosate which provides details of how the panel reached its decision in March.

In light of the IARC classification on glyphosate, diazinon and malathion the WHO/FAO Joint Meeting on Pesticide Residues (JMPR) convened in May 2016 to re-evaluate these compounds and in contrast to IARC found they were "unlikely to pose a carcinogenic risk to humans from exposure through diet".

WHO published a useful explanatory **[HYPERLINK "http://www.who.int/features/qa/87/en/"]** on it's website, which said IARC's hazard identification helped inform the JMPR's risk assessment, and thus the two processes were "complementary". It said: *"Hazard identification – in particular, the IARC classification of substances in terms of their carcinogenicity – is the first step of the risk assessment process. Risk assessment for pesticide residues in food, as conducted by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), establishes a safe intake level after assessing the level of risk."*

Nevertheless, law makers have remained "confused", as highlighted by the recent politically-charged experience in the European Union where certain Member States have called to ban the use of glyphosate on health grounds, based in large part on IARC's classification. This was despite the European Food Safety Authority (EFSA) **[HYPERLINK "http://www.efsa.europa.eu/en/press/news/151112?utm_campaign=engagor&utm_content=engagor_MzgxOTgyMg%3D%3D&utm_medium=social&utm_source=twitter"]** of the active substance glyphosate which concluded glyphosate was "unlikely to pose a carcinogenic hazard to humans". Explaining how it reached a different conclusion, EFSA said it had "assessed more evidence including additional key studies that were not considered by IARC".

Outside of the crop protection industry IARC gained further headlines in October 2015 when it classified red meat as "probably carcinogenic" and processed meat as definitely carcinogenic. Contrary to the fallout of classifications on crop protection products there were no calls for these meat products to be banned. Instead, the WHO clarified that red meat should be part of a balanced diet, highlighting the confusion surrounding the true purpose of an IARC classification.

CropLife International Strategy

CropLife International is working with the global network to coordinate an ongoing strategy which includes the following measures:

Generating influencer commentary on IARC

- To challenge the credibility of IARC and increase awareness of the issues, CropLife International is working with issue management consultancy v-Fluence to generate proactive news/commentary articles published in relevant/influential spaces. The first phase of the strategy involved intelligence gathering on the IARC process, its personnel (secretariat and panel members) and overall methodology for making classifications. The second half of the strategy has involved intelligence sharing with a network of bloggers, commentators and journalists in order to expose inconsistencies, conflicts of interest and transparency issues. A number of positive articles have been published in recent months including articles in the Times of London ([HYPERLINK "http://www.rationaloptimist.com/blog/pseudoscience/"]), Reuters ([HYPERLINK "http://www.reuters.com/investigates/special-report/health-who-iarc/"]) and Daily Mail online ([

HYPERLINK "http://www.dailymail.co.uk/wires/reuters/article-3545353/How-World-Health-Organizations-cancer-agency-confuses-consumers.html"]). There has also been heightened activity on influential blogs including Science 2.0, Forbes, Genetic Literacy Project and Risk Monger. All articles have been pushed widely on social media channels through a wide network of industry commentators.

High level outreach to WHO

- CropLife International has requested several meetings with WHO Director General Margaret Chan to discuss IARC methodology and to ask for greater efforts to clarify the meaning of the IARC classifications, but so far no request has been accepted. However, in May 2016 WHO published a [HYPERLINK "http://www.who.int/features/qa/87/en/"] on its website to explain the important distinction between IARC's hazard identification and the JMPR's risk assessment.
- National associations in the global CropLife network have written to their government ministries using aligned messaging to explain that regulatory risk assessments must be the basis for decisions on pesticides, not hazard-based IARC classifications. National associations have also called on their governments to raise the issue with WHO to better educate regulators on the meaning of IARC's classifications.

Building credible 3rd party support

- CropLife International is supporting building relevant, independent non-commercial third party stakeholders (in particular toxicologists and academics) to create appropriate awareness of the impact of IARC classifications to global scientific and regulatory work. The goal is to have an independent written evaluation questioning the role and value of IARC within the scientific community.

Coordinating industry alignment

- CropLife International has enhanced its issue monitoring capabilities for IARC and will continue to produce updated Issue Alerts to ensure the global network remains fully aware and aligned on the issue as activists continue to capitalize on the classifications. The ad-hoc IARC group will also continue to share day-to-day information as the issue develops and to ensure rapid response to breaking news.

EXHIBIT 5

EXHIBIT 5 A

August 24, 2016

Steven Knott, Designated Federal Official
Office of Science Coordination and Policy (7201M)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Submitted via Regulations.gov; Docket ID: EPA-HQ-OPP-2016-0385

Re: FIFRA Scientific Advisory Panel; Notice of Public Meeting: EPA's evaluation of the carcinogenic potential of Glyphosate; Request for Information and Comments; Docket ID No. EPA-HQ-OPP-2016-0385 (July 26, 2016)

Dear Mr. Knott:

CropLife America ("CLA"), established in 1933, represents the nation's developers, manufacturers, formulators, and distributors of crop protection chemicals and plant science solutions for agriculture and pest management in the United States. Our member companies produce, sell, and distribute crop protection and biotechnology products used by American farmers. CLA supports a rigorous, science-based, and transparent process for government regulation of their member companies' products, representing the interests of its member companies by monitoring legislation, federal agency regulations and actions, and litigation that impacts the crop protection and pest control industries, and participating in such actions when appropriate. CLA is committed to working with the U.S Environmental Protection Agency ("EPA" or "the Agency") as the federal agency responsible for the regulation of pesticides, on matters of importance to CLA member companies and the agricultural community.

On July 26, 2016, EPA published a notice [Federal Register (2016-17707)] of its intent to convene a meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel ("SAP") [EPA-HQ-OPP-2016-0385] to review EPA's evaluation of the carcinogenic potential of glyphosate, a non-selective, phosphonomethyl amino acid herbicide registered to control weeds in various agricultural and non-agricultural settings.[1] CLA members have significant concerns about the convening of the SAP on glyphosate given the extensive, scientifically-based risk assessments of the herbicide undertaken by regulators around the globe beginning with the EPA review and registration of glyphosate in 1974.

[1] 81 Fed. Reg. 48,794 (July 26, 2016).

Representing the Crop Protection Industry

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A. Convening a Meeting of the FIFRA SAP to Review the Carcinogenicity of Glyphosate is Unnecessary and an Inappropriate Use of EPA Resources

For over 40 years, the EPA—and all other regulatory and scientific agencies worldwide that have reviewed glyphosate —have concluded that glyphosate does not pose a cancer risk to humans. This includes the European Commission, the Joint WHO/Food Agricultural Organization, Japan, and Australia.[2] In March 2015, however, after review of only a subset of the glyphosate data previously reviewed by these entities, the International Agency for Research on Cancer (IARC) concluded differently—finding that glyphosate is "probably carcinogenic to humans."[3] That conclusion spurred significant criticism from national regulators who responded that the evidence *did not* support IARC's conclusion. *See, e.g.*, European Food Safety Auth. (EFSA), *Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate*, 13 EFSA J. 4302 (Nov. 12, 2015) ("[G]lyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential . . . .").[4]

Moreover, within the past few months, two additional and significant reports have been published that provide the scientifically appropriate and valid rationale for immediate cancellation of the scheduled SAP. The most recent report of the FAO/WHO Special Session of the JMPR, "Pesticides in Food 2016," in its in-depth review found that glyphosate is unlikely to pose a carcinogenic risk to humans via exposure from diet.[5] This expert meeting was called specifically to assess the differences in reported human health effects (carcinogenicity,

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2 *See, e.g.*, 78 Fed. Reg. 25,396 (May 1, 2013); Scitox Assessment Servs., *A Review of the Eart Open Source (EOS) Report "Roundup and Birth Defects: Is the Public Being Kept in the Dark?"* (July 2013), http://archive.apvma.gov.au/news_media/docs/glyphosate_scitox_review_july_2013.pdf; European Comm'n, Directive 6511/VI/99, *Report for the Active Substance Glyphosate* (Jan. 21, 2002), http://ec.europa.eu/food/fs/ph_ps/pro/eva/existing/list1_glyphosate_en.pdf; *Report of Evaluation by Food Sanitation Council Agricultural Chemicals Residue Committee*, 50 Shokuhin Eisei Kenkyu, No. 8 (2000); WHO/FAO, *Pesticides Residues in Food* 145 (2011), http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Report11/Glyphosate.pdf.

3 Int'l Agency for Research on Cancer, WHO, *Glyphosate*, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, vol. 112 (2015), http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-09.pdf .

4 *See also* Pest Mgmt. Regulatory Agency, Health Canada, *Proposed Re-evaluation Decision PRVD2015-01, Glyphosate* (Apr. 13, 2015), http://www.hc-sc.gc.ca/cps-spc/pest/part/consultations/_prvd2015-01/prvd2015-01-eng.php (overall weight of evidence indicates that glyphosate is unlikely to pose a human cancer risk); Ger. Fed. Inst. for Risk Assessment, *Does Glyphosate Cause Cancer?* (Mar. 23, 2015), http://www.bfr.bund.de/cm/349/does-glyphosate-cause-cancer.pdf. ("[T]he Federal Institute for Risk Assessment (BfR) was responsible for the human health risk assessment and *has assessed glyphosate as non-carcinogenic*. This was supported by competent national, European and other international institutions for health assessment including the WHO/FAO Joint Meeting on Pesticide Residues (JMPR).)"; New Zealand Environmental Protection Agency, *Review of the Evidence Relating to Glyphosate and Carcinogenicity* (Aug. 11, 2016), http://www.epa.govt.nz/Publications/EPA_glyphosate_review.pdf (overall weight of evidence indicates that glyphosate is unlikely to be carcinogenic); Japanese Food Safety Comm'n, http://www.fsc.go.jp/fsciis/meetingMaterial/show/kai20160324no1.

5 FAO/WHO. *Pesticides in Food 2016: Special session of the Joint FAO/WHO meeting on pesticide residues*. FAO Plant Production and Protection Paper: 227. Rome, August 2016.

genotoxicity, and mutagenicity) between historic JMPR expert assessments of glyphosate and those reported by the WHO International Agency for Research on Cancer (IARC) in 2015.[6] The experts reporting in the global report determined that glyphosate is unlikely to pose a carcinogenic risk to humans via exposure from diet.

Even more recently, regulators of the Environmental Protection Authority of New Zealand concluded, "based on a weight of evidence approach, taking into account the quality and reliability of the available data, glyphosate is unlikely to be genotoxic or carcinogenic to humans and does not require classification under HNSO as a carcinogen or mutagen."[7]

The rationale for convening this FIFRA SAP is not the need for more or better data; nor is it the submission of a greater set of animal and *in vitro* data from Part 158-required analyses. In fact, it is clear from the 2015 report of the EPA Cancer Assessment Review Committee (CARC) Report that EPA has no further questions as to the carcinogenicity of glyphosate.[8] EPA rationale for convening the SAP is that it contends there is a need for review of new data that was not available during its previous reviews of glyphosate safety data, and that based on the conclusions of the IARC 2015 glyphosate Monograph 112, more careful review of existing epidemiologic data is needed. However, as recently as October 2015 (months following the publication of the IARC Monograph), the CARC reported, "the epidemiological studies in humans showed no association between glyphosate exposure and cancer of the following: oral cavity, esophagus, stomach, colon, rectum, colorectum, lung, pancreas, kidney, bladder, prostate, brain (gliomas), soft-tissue sarcoma, leukemia or multiple myelomas." What is new for EPA consideration from what was concluded by EPA's own CARC in October 2015?

There is no scientific justification for another EPA review of glyphosate for carcinogenicity when the EPA CARC report of October 2015 found no concerns as to potential carcinogenicity. The EPA must be clear about any further study- and specific about its hypothesis as to what might be an impact that is yet to be considered. The absence of the usual precedent step to convening an SAP—an EPA CARC finding of some concern—raises questions as to the motivation undergirding EPA's intent to reconsider (once again) its previous findings and conclusions.

What's more, the ability of EPA to gather scientists more qualified than those engaged by FAO/WHO and the JMPR to once again review the scientific literature is unlikely. The Notice to convene the FIFRA SAP on glyphosate invites nominations of candidates to serve as *ad hoc* members of FIFRA SAP, which is to convene October 18, 2016 through October 21, 2016 (the "October 2016 meeting").

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6 World Health Organization. 2015. International Agency for Research on Cancer, Monograph on Glyphosate. Volume 112. Geneva Switzerland.

7 New Zealand Environmental Protection Agency, *Review of the Evidence Relating to Glyphosate and Carcinogenicity* (Aug. 11, 2016), http://www.epa.govt.nz/Publications/EPA_glyphosate_review.pdf (overall weight of evidence indicates that glyphosate is unlikely to be carcinogenic).

8 EPA. Office of Chemical Safety and Pollution Prevention 2015. Glyphosate: Report of the Cancer Assessment Review Committee. October 1 2015, Washington DC.

EPA is legally obligated to exclude industry members whose conflicts of interest and established biases preclude their ability to impartially contribute to the panel's final report, conclusions of which likely will inform regulatory determinations in the near term. CLA therefore opposes the selection of any *ad hoc* members who have already made a determination regarding the carcinogenic potential of glyphosate.

B. The EPA Has an Obligation to Ensure the Impartiality of the FIFRA SAP

The Federal Advisory Committee Act (FACA) imposes strict conflict of interest requirements on the FIFRA SAP selection process.[9] EPA must ensure that the FIFRA SAP acts "in the public interest,"[10] and does not contain members with inappropriate special interests.[11] To meet the requirements established by FACA, the FIFRA SAP shall be comprised of impartial experts capable of providing an independent review of data on the carcinogenic potential of glyphosate. Indeed, the Office of Government Ethics advises against the participation of SAP panel members whose participation will create even the "appearance of loss of impartiality."[12]

Historically, EPA has placed a premium on expertise, knowledge and experience in the field when selecting members for its advisory committees.[13] The EPA SAP office has adopted conflict of interest rules for the selection of committee members, which aim to exclude those who "might be unable to provide impartial advice or [whose] impartiality in the particular matter might be questioned."[14] If a conflict exists between a panel candidate's private financial interests and duties as a panel member, EPA will, as a rule, seek to appoint another candidate instead.[15] Grounds for exclusion from a committee include performing consulting activities or providing expert testimony regarding an issue relating to that presented before the SAP.[16] Potential ad hoc members may also be excluded based on, *inter alia,* experience with the topic under consideration that suggests an established position or implicates an inability to render

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9 *See* 5 U.S.C. App. II, § 3(2).

10 S*ee id.* App. II, § 9(a)(2).

11 *See id.* § 5(b)(3).

12 5 C.F.R. § 2635.501(a) (2016); *see also* Sci. Advisory Bd., EPA, *Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board* 9-10 (Sept. 2002), https://yosemite.epa.gov/sab/sabproduct.nsf/WebFiles/OverviewPanelForm/$File/ec02010.pdf [hereinafter "*Overview of Panel Formation*"]; *see also* 18 U.S.C. §202(a); Sci. Advisory Bd., EPA, *Ethics for Advisory Committee Members*, https://yosemite.epa.gov/sab/sabproduct.nsf/Web/ethics?OpenDocument (last updated May 3, 2016).

13 *Overview of Panel Formation*, *supra* note 12, at 9 (listing "[e]xpertise, knowledge, and experience" as "primary factors that determine whether an individual is invited to serve on an SAB Panel").

14 *See* EPA, *Information on the Panel Formation Process for the EPA FIFRA SAP* (Sept. 16, 2004), http://www.epa.gov/sites/production/files/2015-06/documents/srb_process_interviews.pdf [hereinafter "*Panel Formation Process for the EPA FIFRA SAP*"]; 81 Fed. Reg. at 48,795.

15 *See Overview of the Panel Formation*, *supra* note 12, at 9-10.

16 *See Panel Formation Process for the EPA FIFRA SAP*, *supra* note 14, at 5-8.

impartial advice; evidence of partial "public statements on the issue"; and, evidence of financial conflicts of interest.[17]

The inclusion of scientists who are not impartial—or who have lost their appearance of impartiality—is counter to EPA's goal of assembling a panel of experts to provide sound, independent, and useful scientific and technical advice.[18] EPA therefore should not appoint to the FIFRA SAP any person who has publicly expressed an opinion regarding the carcinogenicity of glyphosate.

C. Representatives Who Are Not Impartial Must Not Participate as Ad Hoc Members of the FIFRA SAP

The IARC process and subsequent events revealed the pre-formed conclusions and conflicts of interest of several scientists with respect to the evaluation of the carcinogenic potential of glyphosate. By way of example, Dr. Kathryn Guyton, one of the lead IARC scientists, presented speeches to NGO groups both before and upon completion of the IARC review in which she stated that glyphosate is linked to breast cancer.[19] Dr. Christopher Portier served as the "technical advisor" to the IARC glyphosate review panel, and following publication of the IARC monograph, sought to induce regulatory agencies worldwide to adopt IARC's conclusions by undertaking a publicity campaign using letter-writing initiatives, articles and publications, and direct advocacy before regulatory bodies.[20] Dr. Portier has regularly engaged in policy advocacy against glyphosate since IARC's findings were published.[21]

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17 *See id.* at 5-8, 10-14.

18 *See* EPA Sci. Advisory Bd., *supra* note 12, at 9.

19 *See, e.g.*, David Zaruck & Julie Kelly, *'The Facebook Age of Science' at the World Health Organization*, Nat'l Review (May 3, 2016), http://www.nationalreview.com/article/434845/WHO-cancer-agency-bad-science-labels-glyphosate-probably-carcinogenic.

20 As one example, Mr. Portier pleaded with the European Food Safety Authority ("EFSA") to rethink their own findings that glyphosate does not "pose a carcinogenic hazard to humans." Christopher Portier et al., *Open Letter: Review of the Carcinogenicity of Glyphosate by EFSA and BfR*, (Nov. 27, 2015) *available at* http://www.zeit.de/wissen/umwelt/2015-11/glyphosat-offener-brief.pdf [hereinafter "*Open Letter: Review of the Carcinogenicity of Glyphosate by EFSA and BfR*"]. *See also* Christopher Portier et al., *Difference in the Carcinogenic Evaluation of Glyphosate Between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA)*, J. Epidemiol Community Health (2016) [hereinafter "*Differences Study*"].

21 In speaking to the Soil Association, for instance, Mr. Portier exaggerated the findings of the IARC report, stating that "Glyphosate is definitely genotoxic. *There is no doubt in my mind*." Curt DellaValle, *Monsanto's GMO Weed Killer Damages DNA*, AgMag (July 17, 2015), http://www.ewg.org/agmag/2015/07/monsanto-s-gmo-weed-killer-damages-dna; *see also* Sustainable Pulse, *WHO Cancer Expert: Glyphosate is Definitely Genotoxic* (July 15, 2015) http://sustainablepulse.com/2015/07/15/who-cancer-expert-glyphosate-is-definitely-genotoxic/. Tellingly, Mr. Portier himself questioned his impartiality with respect to the matter in question. In response to a question about his work with EDF and his research into glyphosate, Mr. Portier responded, "I agree that this has the appearance of being a conflict of interest." Kate Kelland, *How the World Health Organization's Cancer Agency Confuses Consumers*, Reuters (Apr. 18, 2016), http://www.reuters.com/investigates/special-report/health-who-iarc/.

Drs. Guyton and Portier serve as only two examples of scientists with disqualifying biases for the purposes of appointment to the FIFRA SAP October panel. No scientist who has authored or contributed to the IARC monograph or who has advocated to the European Union that IARC's review is superior to that of other regulatory bodies[22] should participate in EPA's upcoming review of glyphosate's carcinogenicity.

Nor should the FIFRA SAP include those individuals who have made "written or oral public statements indicating the candidate has already formed a position on the topic."[23] Such individuals include signatories to the "Stop Glifosate" initiative[24] and authors of "Concerns Over Use of Glyphosate-based Herbicides and Risks Associated with Exposures: A Consensus Statement."[25] The bias born of expressing a public conclusion on a scientific topic compromises the ability of these individuals to deliver dispassionate, determinative scientific analysis and advice to EPA.

Finally, the FIFRA SAP should also exclude scientists who have a direct stake in final determinations of the FIFRA SAP on this issue.[26] Scientists with a profit motivation that could be affected by the outcome of this process may seek to downplay the toxic effects of glyphosate on human health and well-being, or conversely, overemphasize or focus solely upon the benefits of glyphosate, consistent with the well-being of an employer. For example, Dr. Portier serves as an expert in litigation on behalf of plaintiffs who argue that glyphosate causes cancer.[27] Dr. Portier therefore has a direct profit motivation in the outcome of the FIFRA SAP deliberations.

It is EPA's charge to ensure the credibility of its determinations, particularly where the question regards a topic of great interest to the public health and environmental community. The work of the ad hoc panel members in this October 2016 meeting of the FIFRA SAP will be critical to the determinations of the panel. Accordingly, EPA should reject any nominees who have any direct or potential conflicts of interest or industry bias, or offer the appearance of partiality, on the question of the carcinogenicity of glyphosate.

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22 *See, e.g., Open Letter: Review of the Carcinogenicity of Glyphosate by EFSA and BfR*, *supra* note 20.

23 *See Panel Formation Process for the EPA FIFRA SAP*, *supra* note 14, at 16.

24 *See Stop Glifosato*, http://www.stopglifosato.it/ (last visited Aug. 11, 2016). The StopGlifosate campaign began in 2015. The campaign's signatories and supporters, such as Italy's Ramazzini Institute, publically endorse the IARC's challenged classification of glyphosate as "likely carcinogenic" to humans. *Id.*

25 Myers et al. "Concerns Over Use of Glyphosate-based Herbicides and risks Associated with Exposures: A Consensus Statement," 15 Envtl. Health, no. 19 (2016).

26 This is consistent with the advice of the National Academies, which has stated "it is essential that the work of committees … not be compromised by issues of bias and lack of objectivity … . Questions of lack of objectivity and bias ordinarily relate to views, statements, or positions taken that are largely individual with a particular point of view or the positions or perspectives of a particular group." Nat'l Acad. of Scis., *Policy on Committee Composition and Balance and Conflicts of Interest* 4 (2003).

27 *See Differences Study*, *supra* note 20, at p. 4 ("Competing interests").

Thank you for your consideration of these comments.

Respectfully submitted,

Janet E. Collins, Ph.D., R.D., CFS
Senior Vice President
Science and Regulatory Affairs

Cc: Mr. Steven Knott

EXHIBIT 5 B

October 12, 2016

Steven Knott, Designated Federal Official
Office of Science Coordination and Policy (7201M)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Submitted via Electronic Mail to Knott.Steven@epa.gov and via Regulations.gov; Docket ID: EPA-HQ-OPP-2016-0385

Re: FIFRA Scientific Advisory Panel; Notice of Public Meeting: EPA's evaluation of the carcinogenic potential of Glyphosate; Request for Information and Comments; Docket ID No. EPA-HQ-OPP-2016-0385 (July 26, 2016)

Dear Mr. Knott:

CropLife America ("CLA"), established in 1933, represents the nation's developers, manufacturers, formulators, and distributors of crop protection chemicals and plant science solutions for agriculture and pest management in the United States. Our member companies produce, sell, and distribute crop protection and biotechnology products used by American farmers. CLA members support a rigorous, science-based, and transparent process for government regulation of their products, representing the interests of its member companies by monitoring legislation, federal agency regulations and actions, and litigation that impacts the crop protection and pest control industries, and participating in such actions when appropriate. CLA is committed to working with the U.S Environmental Protection Agency ("EPA" or "the Agency"), as the federal agency responsible for the regulation of pesticides, on matters of importance to CLA member companies, the agricultural community and the general public.

On July 26, 2016, EPA published notice in the federal register of its intention to convene a meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel ("FIFRA SAP") to review EPA's evaluation of the carcinogenic potential of glyphosate, a non-selective, phosphonomethyl amino acid herbicide registered to control weeds in various agricultural and non-agricultural settings.[1] The notice invites nominations of candidates to serve as ad hoc members of the FIFRA SAP, which is to convene October 18, 2016 through October 21, 2016 (the "October 2016 meeting").

[1] FIFRA, Scientific Advisory Panel 81 Fed. Reg. 48,794 (Meeting July 26, 2016).

Under FIFRA, the SAP serves in an advisory role and provides "comment[s] as to the impact on health and the environment" of registrations being considered by EPA.[2] All final decision-making authority under FIFRA rests with EPA. Pursuant to its authority under FIFRA, EPA has previously concluded that glyphosate is "not likely to be carcinogenic to humans."[3]

As CLA explained in its August 17, 2016 letter ("Conflicts Letter"), EPA is legally obligated to exclude scientists from the SAP whose conflicts of interest or established biases preclude their ability to contribute impartially to the panel's final report. CLA therefore respectfully opposes the selection of Dr. Peter Infante, whose patent biases should disqualify him from service on the SAP. CLA also asks EPA to take note of certain information regarding Dr. Kenneth Portier and confirm his ability to participate without any pre-formed conclusions, although it does not seek his disqualification.

The EPA Has an Obligation to Ensure the Impartiality of the FIFRA SAP

The Federal Advisory Committee Act (FACA) imposes strict conflict of interest requirements on the FIFRA SAP selection process.[4] As explained in greater detail in CLA's Conflicts Letter, EPA must ensure that the FIFRA SAP acts "in the public interest,"[5] and does not contain members with inappropriate special interests.[6] To meet the requirements established by FACA, the FIFRA SAP shall be comprised of impartial experts capable of providing an independent review of data on the carcinogenic potential of glyphosate. Indeed, the Office of Government Ethics advises against the participation of SAP panel members whose participation will create even the "appearance of loss of impartiality."[7]

To implement FACA's mandate, the EPA SAP office has adopted conflict-of-interest and bias rules for the selection of committee members, which aim to exclude those who "might be unable to provide impartial advice or [whose] impartiality in the particular matter might be questioned."[8] Among other requirements, "appearance of lack of impartiality, lack of independence, and bias may result in disqualification."[9]

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[2] 7 U.S.C. § 136w

[3] *See*, EPA's Office of Pesticide Programs, *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* at 141 (2016).

[4] *See* 5 U.S.C. App. II, § 3(2).

[5] *See id*. App. II, § 9(a)(2).

[6] *See id.* § 5(b)(3).

[7] 5 C.F.R. § 2635.501(a) (2016); *see also* Sci. Advisory Bd., EPA, *Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board* 9-10 (Sept. 2002), https://yosemite.epa.gov/sab/sabproduct.nsf/WebFiles/OverviewPanelForm/$File/ec02010.pdf; *see also* 18 U.S.C. §202(a); Sci. Advisory Bd., EPA, *Ethics for Advisory Committee Members*, https://yosemite.epa.gov/sab/sabproduct.nsf/Web/ethics?OpenDocument (last updated May 3, 2016).

[8] *See* EPA, *Information on the Panel Formation Process for the EPA FIFRA SAP* 16 (Sept. 16, 2004), http://www.epa.gov/sites/production/files/2015-06/documents/srb_process_interviews.pdf [hereinafter "Panel Formation Process for the EPA FIFRA SAP"]; 81 Fed. Reg. at 48,795.

[9] *See id.* at 5-8, 10-14.

Dr. Infante's Biases Should Disqualify Him From Service on the Glyphosate SAP

EPA's ethical rules should preclude Dr. Infante's participation in the glyphosate SAP. Dr. Infante is a member of Collegium Ramazzini,[10] which has taken radical anti-pesticide positions, such as calling for a prohibition on all "pesticide use in all public areas, including residential areas and recreation grounds," even if regulatory agencies have concluded such uses were safe.[11] Dr. Infante has also repeatedly testified—exclusively for plaintiffs—in chemical exposure cases against Monsanto Company, the original registrant of glyphosate, and its affiliated entities.[12]

Even more troubling, federal courts have concluded that Dr. Infante has engaged in a pattern of biased, results-oriented analysis that disqualified consideration of his opinions. Of particular note is a decision of the Eastern District of Louisiana, which struck his testimony in a thoughtful and comprehensive opinion. *See Burst v. Shell Oil Co.,* No. 14-109, 2015 WL 3755953 (E.D. La. June 16, 2015). Judge Vance's *Burst* decision leaves little doubt that Dr. Infante is all-too-willing to manipulate scientific analysis to reach pre-determined outcomes (*i.e.*, invariably concluding a chemical is unsafe). In *Burst*, she explained that Dr. Infante's analysis "suggest[ed] a methodology driven by an attempt to achieve a particular result," *id.* at *14, which was apparent in several respects:

- "[I]n several instances, ***Dr. Infante cherry-picked data*** from studies that did not otherwise support his conclusion, ***failed to explain contrary results***, ***reached conclusions the authors of the study did not themselves make***, and ***manipulated data*** without providing any evidence of his work." *Id.* at 10 (emphasis added).

- "Dr. Infante cherry-picks data from studies in several significant instances and fails to explain contrary results in a manner that belies the reliability of his methodology." *Id.* at *13.

- The court dryly observed that: "Absent from Dr. Infante's report is any acknowledgment that this study separately examined the risk for [the specific cancer at issue] and did not find a statistically significant increased risk. The Court can only speculate as to why Dr. Infante neglected to discuss this pertinent finding in his report." *Id.* at *13.

- "[I]t is clear that Dr. Infante relied on a universe of divergent studies that either did not examine the substance at issue, did not examine the disease at issue, or did not exhibit statistically significant results. Moreover, ***Dr. Infante exhibited a willingness to ignore***

[10] *See* http://www.collegiumramazzini.org/fellows1.asp?id=82

[11] *See* Collegium Ramazzini Statement, The Control of Pesticides in the European Union: A Call for Action to Protect Human Health (2008) available at http://www.collegiumramazzini.org/download/13_ThirteenthCRStatement(2008).pdf

[12] *See* Roney v. GenCorp, et. al., No. 05-cv-788 (S.D.W. Va. 2005); Taylor v. Airco, Inc., et. al., No. 02-30014-MAP (D. Mass. 2002); Lewis v. Airco, Inc., et. al., No. L-10503-02 (N.J. Civ. Div., Essex County 2002); Skeen, et. al. v. Monsanto Company, No. G-82-468 (S.D. Tex. 1982).

> ***or disregard contrary results, and to manipulate data*** in a manner not supported by any evidence of his work or independent justification and, in one instance, inconsistent with the authors' own discussion." *Id.* at *16 (emphasis added).

Judge Vance also cast doubt on Dr. Infante's scientific rigor. In response to the court's question about an obvious gap in his analysis, the court noted: "At the hearing, Dr. Infante explained that he *performed the [relevant] calculation on a 'sticky note.'*" *Id.* at *14 (emphasis added).

Burst is not an outlier. The Eastern District of Washington has similarly struck Dr. Infante's testimony and noted his obvious willingness to disregard studies that contradicted his opinions. *See Henricksen v. Conoco Phillips Co.*, 605 F. Supp. 2d 1142, 1168–77 (E.D.Wa. 2009) ("[T]here is simply too great an analytical gap between the data presented and the opinions offered … such that it renders the expert testimony too speculative as a matter of law.; *id.* at 1172 (noting important study supporting contrary conclusion was conspicuously "not cited by Dr. Infante"); *id.* at 1174 (noting that while study at issue was updated "notably, Dr. Infante did not cite [the update] in his report").

Dr. Infante's public—and colorful— statements also indicate he will reflexively discount any and all industry-sponsored studies and lacks the temperament for unbiased analysis of glyphosate. Dr. Infante notably contributed to a 2014 book titled: *Our Daily Poison: From Pesticides to Packaging, How Chemicals Have Contaminated the Food Chain and Are Making Us Sick*, authored by Marie-Monique Robin (who also authored the anti-Monsanto book *The World According to Monsanto*). In *Our Daily Poison*, Dr. Infante:

- Expressed his disdain for all industry-sponsored studies, stating: "How does industry find scientists to do this kind of task? It buys them, that's all! Let's be clear—***it's what I call 'prostituted science.***'" *Id.* at 144 (emphasis added).

- Expressed his view that regulatory agencies are chronically incapable of evaluating industry-sponsored studies properly: "***The problem is that biased studies are then sent to regulatory agencies, who take them at face value***. That's how highly toxic substances have been contaminating our environment, our food, our fields or our factories, for decades." *Id.* (emphasis added).

- "Generally, studies sponsored by industry have been designed in such a way that it is nearly impossible to find harmful effects. The consequence is ***that the scientific literature is regularly polluted by worthless studies***. It's pathetic." *Id.* at 141 (emphasis added).

The glyphosate SAP is certain to consider industry-sponsored studies as part of its proceedings and there is no reason to believe that Dr. Infante will consider such studies as anything other than "prostituted science" and "worthless," as he has in the past. Dr. Infante's incendiary statements manifestly demonstrate that his "impartiality in the particular matter might be questioned."

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The prejudice from Dr. Infante's bias is particularly acute because he is currently the only epidemiologist on the glyphosate SAP, potentially enhancing his ability to influence the SAP proceedings improperly. Because of the potential importance of epidemiological data, EPA should replace Dr. Infante with an epidemiologist without such patent bias.

For all of these reasons, CLA respectfully requests that Dr. Infante be excluded from participation in the glyphosate SAP.

EPA Should Confirm That Dr. Kenneth Portier Will Participate Without Any Pre-Formed Conclusions.

Although he has not previously testified against or otherwise expressed the patent bias against pesticide manufacturers or the science upon which they and/or regulatory bodies rely, Dr. Portier has expressed opinions about glyphosate that suggest he may already have pre-formed conclusions as to glyphosate's safety. For example, Dr. Portier has stated that "glyphosate needs to go on the California Prop. 65 database" of chemicals that may cause cancer or have reproductive toxicity.[13] Dr. Portier has also urged "manufacturers to come up with alternative products" to glyphosate because, in his view, "We don't like to see man-made carcinogens freely circulating in the environment."[14]

Dr. Portier is also the brother of Dr. Christopher J. Portier, a noted and vehement anti-glyphosate activist. CLA requests that EPA confirm that his brother's views will not affect Dr. Portier's ability to evaluate the relevant evidence objectively and that he has not already formed a conclusion regarding the carcinogenicity of glyphosate.

Respectfully submitted,

Janet E. Collins

Janet E. Collins, Ph.D., R.D., CFS
Senior Vice President
Science and Regulatory Affairs

[13] *See* Interview with Dr. Kenneth Portier on Smart Health Talk (Oct. 27, 2015) *available at* http://www.smarthealthtalk.com.

[14] *See* Dennis Thompson, *Genetically Modified Foods, Herbicides and Human Safety*, HealthDay (Aug. 19, 2015) *available at* https://consumer.healthday.com/vitamins-and-nutrition-information-27/food-and-nutrition-news-316/herbicides-and-gmos-702482.html.

EXHIBIT 6

Message

From: MURPHEY, SAMUEL [AG/1000] [samuel.murphey@monsanto.com]

Sent: 1/21/2016 8:49:21 PM

To: HEERING, DAVID C [AG/1000] [david.c.heering@monsanto.com]; PLEYSIER, ANNICK [AG/5040] [annick.pleysier@monsanto.com]; SILVEIRA, LUIZ [AG/5050] [luiz.silveira@monsanto.com]; BERGER, GERALDO U [AG/5050] [geraldo.u.berger@monsanto.com]; LISTELLO, JENNIFER J [AG/1000] [jennifer.j.listello@monsanto.com]; WAKIMORI, HIROO [AG/5270] [hiroo.wakimori@monsanto.com]; KIPLAGAT, BETTY [AG/6043] [betty.kiplagat@monsanto.com]; GUSTIN, CHRISTOPHE [AG/5040] [christophe.gustin@monsanto.com]; PARRISH, MICHAEL [AG/1000] [michael.parrish@monsanto.com]; WANG, LIRU [AG/6000] [liru.wang@monsanto.com]; TREACY, BRIAN K [AG/8070] [brian.k.treacy@monsanto.com]; OYHANARTE, HORACIO [AG/5000] [horacio.oyhanarte@monsanto.com]; JORDAN, TRISH L [AG/5125] [trish.l.jordan@monsanto.com]; PIRES, CATHARINA E [AG/5050] [catharina.e.pires@monsanto.com]; VAUGHN, TY T [AG/1000] [ty.t.vaughn@monsanto.com]; GIANNONI, FERNANDO HUGO [AG/5000] [fernando.hugo.giannoni@monsanto.com]; YOON, SUN KYOUNG [AG/5340] [sun.kyoung.yoon@monsanto.com]; REBMAN, JOHN [AG/1000] [john.rebman@monsanto.com]; JENKINS, DANIEL J [AG/1920] [daniel.j.jenkins@monsanto.com]; MURPHY, STEPHANIE L [AG/1920] [stephanie.l.murphy@monsanto.com]; SOUZA, MARIA CLAUDIA [AG/5050] [maria.claudia.souza@monsanto.com]; EKE, KEVIN H [AG/5340] [kevin.h.eke@monsanto.com]; DUBEY, RAKESH [AG/6020] [rakesh.dubey@monsanto.com]; TRAVIS, JAMES K [AG/1920] [james.k.travis@monsanto.com]; MANNY, VICTORIA [AG/5000] [victoria.manny@monsanto.com]; MARTINO-CATT, SUSAN J [AG/1000] [susan.j.martino-catt@monsanto.com]; ALVAREZ ARANCEDO, MIGUEL [AG/5000] [miguel.alvarez.arancedo@monsanto.com]; HIDE, ALISTAIR [AG/6042] [alistair.hide@monsanto.com]; JACOBS, ERIK [AG/1000] [erik.jacobs@monsanto.com]; NAGAR, PIYUSH [AG/6020] [piyush.nagar@monsanto.com]; DUNCAN, MELISSA S [AG/1000] [melissa.s.duncan@monsanto.com]; RAMSAY, JONATHAN [AG/5040] [jonathan.ramsay@monsanto.com]; GAO, YONG [AG/6000] [yong.gao@monsanto.com]; DYKES, MICHAEL D [AG/1920] [michael.d.dykes@monsanto.com]; ZHANG, LING [AG/6000] [ling.zhang@monsanto.com]; SAMUEL, CHRISTOPHER [AG/5340] [christopher.samuel@monsanto.com]; FORSTER, AMANDA [AG/5340] [amanda.forster@monsanto.com]; BAE, NICOLE [AG/2660] [nicole.bae@monsanto.com]; LOZANO, JOSE ALFONSO [AG/7879] [jose.alfonso.lozano@monsanto.com]; LYNCH, JOHN A [AG/8070] [john.a.lynch@monsanto.com]; SASAKI, YUKIE [AG/5270] [yukie.sasaki@monsanto.com]; GARNETT, RICHARD P [AG/5040] [richard.p.garnett@monsanto.com]; TURNER, CHRISTOPHER J [AG/1000] [christopher.j.turner@monsanto.com]; DAS, ARNAB [AG/6020] [arnab.das@monsanto.com]; REYNOLDS, TRACEY L [AG/1000] [tracey.l.reynolds@monsanto.com]; AGUSTIN, MELISSA [AG/1000] [melissa.agustin@monsanto.com]; PEREZ PICO, EDUARDO [AG/7879] [eduardo.perez.pico@monsanto.com]; WATERS, STEPHEN P [AG/5040] [stephen.p.waters@monsanto.com]; RANGWALA, TASNEEM S [AG/1000] [tasneem.s.rangwala@monsanto.com]; SURESH, P J [AG/8036] [p.j.suresh@monsanto.com]; TAMAYO, LAURA [AG/7879] [laura.tamayo@monsanto.com]; JOHNSON, KEHINDE [AG-Contractor/6042] [KJOHN3@monsanto.com]; CARPINTERO, DAVID [AG/5040] [david.carpintero@monsanto.com]; CANCADO, OTAVIO H [AG/5050] [otavio.h.cancado@monsanto.com]

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Subject: Heads-up: Prop 65 legal action

Attachments: 2016-01-21 ISSUE ALERT Monsanto Takes Legal Action to Prevent Prop 65 Listing of Glyphosate.pdf

Global colleagues –

Earlier today, Monsanto filed a lawsuit against the California Office of Environmental Health Hazard Assessment (OEHHA). An Issue Alert with key messages, FAQs and resources is below. We are executing a proactive mainstream and social media effort to amplify our messages on this lawsuit, and we expect that the filing will receive coverage. Reuters has issued a brief news alert here, and we expect a more detailed story to follow. Our full media statement is available here; a piece on the Beyond the Rows blog is available here.

Please use the messages and resources in the Issue Alert to respond to inquiries from your stakeholders. We will provide updates to you later today and tomorrow on the overall volume and tone of media coverage.

Please feel free to contact me with any questions.

Regards,

Sam

From: NEWSDESK, HELP [AG/1000]
Sent: Thursday, January 21, 2016 2:41 PM
Subject: ISSUE ALERT: Monsanto Takes Legal Action to Prevent Prop 65 Listing of Glyphosate

FOR INTERNAL INFORMATION ONLY - NOT FOR EXTERNAL DISTRIBUTION

MONSANTO COMPANY CONFIDENTIAL

DATE: January 21, 2016

ISSUE ALERT: Monsanto Takes Legal Action to Prevent Prop 65 Listing of Glyphosate

BACKGROUND:

Monsanto today took legal action against the California Office of Environmental Health Hazard Assessment (OEHHA) to prevent the state agency from listing glyphosate under the state's Proposition 65 as a chemical "known to the state of California to cause cancer." On Sept. 4, 2015, OEHHA announced its intention to add glyphosate to the Prop 65 list. The proposed listing is an action by a California state agency and not the U.S. EPA. Monsanto and a broad

range of agricultural, industrial and scientific stakeholders strongly disagree with the state's intention, and Monsanto has asked the court to prohibit OEHHA from adding glyphosate to the Prop 65 list.

The state's proposed listing of glyphosate would be flawed and baseless because glyphosate does not cause cancer, as has been concluded by the U.S. EPA, the European Food Safety Authority and pesticide regulators around the world. The listing would violate the California and U.S. Constitutions because the state would be ceding the basis of its regulatory authority to an unelected and non-transparent foreign body that is not under the oversight or control of any federal or state government entity.

Indeed, OEHHA, the very state agency that now intends to add glyphosate to the Prop 65 list, determined in 2007, after conducting a rigorous and science-based assessment, that glyphosate was unlikely to cause cancer. In striking contrast, OEHHA now interprets Prop 65 to require the agency to accept the erroneous classification of glyphosate as a "probable carcinogen" by an ad hoc working group of the International Agency for Research on Cancer (IARC), based in Lyon, France, as the **sole** basis for the proposed listing. This interpretation of Prop 65 is unconstitutional.

Moreover, IARC's governing documents specifically disavow any policy- or law-making role for its classifications, and it does not intend its classifications to carry the force of law. **As stated in IARC's preamble, "These evaluations represent only one part of the body of information on which public health decisions may be based. ... Therefore, no recommendation is given with regard to regulation or legislation, which are the responsibility of individual governments or other international organizations."**

Regulatory agencies around the globe, such as the U.S. EPA and EFSA, evaluate pesticides, including glyphosate, using thorough and robust risk assessments based on internationally recognized toxicological principles. As required by the law, these evaluations consider **all** relevant scientific data to arrive at a conclusion about whether a pesticide poses a cancer risk to humans. A routine U.S. EPA registration review on glyphosate opened in 2009 and remains underway.

Since the initial announcement of the IARC meeting's classification in March 2015, multiple regulatory bodies have publicly affirmed that glyphosate does not cause cancer:

- **U.S. EPA**: "Our review concluded that this body of research does not provide evidence to show that glyphosate causes cancer, and it does not warrant any change in EPA's cancer classification for glyphosate." U.S. EPA, Statement from Carissa Cryan, Chemical Review Manager, 2015 (in reference to 55 epidemiological studies evaluated by EPA in 2014). This conclusion was reiterated in testimony by EPA's Deputy Director for Pesticide Programs, William Jordan, before the U.S. Senate Committee on Agriculture, Nutrition and Forestry on Oct. 21, 2015.
- **European Food Safety Authority**: "Glyphosate did not present genotoxic potential and no evidence of carcinogenicity was observed in rats or mice." European Food Safety Authority, *Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate*, 2015
- **Canadian Pest Management Regulatory Authority**: "In consideration of the strength and limitations of the large body of information on glyphosate ... the overall weight of evidence indicates that glyphosate is unlikely to pose a human cancer risk. This is consistent with all other pesticide regulatory authorities world-wide, including the most recent ongoing comprehensive re-evaluation by Germany. ..." Canadian Pest Management Regulatory Authority, *Proposed Re-Evaluation Decision, PRVD2015-01, Glyphosate*, 2015

The members of the ad hoc IARC working group are hand-picked and conduct their assessment in a non-transparent process that is not accountable to the laws or governments of the United States or the State of California. Unlike regulatory risk assessments, the IARC classification process followed non-standard procedures and selectively included and interpreted only a subset of the data actually available on glyphosate.

Monsanto filed the suit against OEHHA today in California's Fresno Superior Court.

ACTION:

Please use the information in this issue alert to respond to inquiries from stakeholders and allies. Please encourage agriculture and industry stakeholders to continue to speak out in support of glyphosate and in opposition to the listing of glyphosate under Prop 65.

CONTACTS:

- Media – **Charla Lord:** 314-694-2993
- Legal – **John Rebman:** 314-694-5043
- Issues Management– **Sam Murphey:** 314-694-4593

KEY MESSAGES:

- Glyphosate does not cause cancer, so listing glyphosate under California's Prop 65 is not warranted scientifically and causes unwarranted concern for consumers. Based on the overwhelming weight of evidence, regulatory agencies have concluded for more than 40 years that glyphosate can be used safely.
- The listing would violate the California and U.S. Constitutions because the state would be ceding the basis of its regulatory authority to an unelected and non-transparent foreign body that is not under the oversight or control of any federal or state government entity.
- The conclusion from the IARC meeting in France was erroneous, non-transparent and based on selectively interpreted data. We are bringing this challenge forward because this intention to list is contrary to science.
- The sole basis of the proposed Prop 65 listing is the classification of glyphosate as a "probable carcinogen" by IARC. The IARC classification of glyphosate is inconsistent with the findings of regulatory bodies in the United States and around the world, and it is not a sound basis for regulatory action.
- Glyphosate is an efficient, effective and safe tool for weed control in fields, along roadways and in other environments.
- We urge the court to prohibit OEHHA from listing glyphosate under Prop 65, and we urge the state of California to reconsider this proposed erroneous listing and uphold its own science-based conclusion about glyphosate and the conclusions of the U.S. EPA and all other pesticide regulators.

Q&A:

Q1. What action has OEHHA taken?

A1. On Sept. 4, OEHHA announced its intention to add glyphosate to the state's Proposition 65 "list of chemicals known to the state of California to cause cancer."

Q2. What legal remedy is Monsanto seeking?

A2. Monsanto is taking legal action to ask the courts to prohibit OEHHA from listing glyphosate under Prop 65. Monsanto asks the court to issue a writ of mandate prohibiting OEHHA from adding glyphosate to the Prop 65 list; to issue a judicial declaration that the so-called "Labor Code" listing mechanism as applied to the proposed listing of glyphosate violates the California and U.S. Constitutions; and to issue preliminary and permanent injunctions enjoining OEHHA from listing or taking any further action to list glyphosate under Prop 65 pursuant to the Labor Code mechanism.

Q3. Why does OEHHA intend to list glyphosate under Prop 65?

A3. The sole basis for OEHHA's intention to list is the flawed classification of glyphosate as a "probable carcinogen" by IARC. Based on OEHHA's interpretation of certain provisions within Prop 65, the agency believes it must simply rubber-stamp the IARC classification of glyphosate as the basis for listing while ignoring their own review and conclusions from 2007. Monsanto strongly disagrees with this interpretation and the intention to list glyphosate.

Q4. What is the basis of Monsanto's argument against listing?

A4. Glyphosate does not cause cancer. Therefore, listing glyphosate under Prop 65 is not appropriate based on science. No pesticide regulatory agency in the world considers glyphosate to be a carcinogen. OEHHA itself even determined in 2007 that glyphosate is "unlikely to be a carcinogen." The listing would also violate the California and U.S. Constitutions because the state would be ceding the basis of its regulatory authority to an unelected and non-transparent foreign body that is not under the oversight or control of any federal or state government entity.

Q5. Would listing under Prop 65 have an impact on labeling requirements or sales in California?

A5. We are considering the full implications of listing under Prop 65. However, we feel strongly that the proposed listing is unfounded, and that is why we are bringing this legal challenge forward. Our goal is to minimize any unnecessary impact on glyphosate's availability in California.

Q6. Is this action by OEHHA connected to the U.S. EPA or the registration review of glyphosate?

A7. No. The proposed listing is not an action by the U.S. EPA, and it is not connected to the ongoing registration review of glyphosate whatsoever. This is solely an action of a California state agency, the Office of Environmental Health Hazard Assessment, which is a unit of the California Environmental Protection Agency (CalEPA).

Q7. What have regulatory agencies said about glyphosate and cancer?

A7. Glyphosate has been on the market for more than 40 years. No regulatory agency in the world considers glyphosate to be a carcinogen. In fact, three regulatory agencies have publicly affirmed that glyphosate does not cause cancer since the initial announcement from the IARC meeting in March 2015:

— "Our review concluded that this body of research does not provide evidence to show that glyphosate causes cancer, and it does not warrant any change in EPA's cancer classification for glyphosate." **U.S. EPA**, Statement from Carissa Cryan, Chemical Review Manager, 2015 (in reference to 55 epidemiological studies evaluated by EPA in 2014). This conclusion was reiterated in testimony by EPA's Deputy Director for Pesticide Programs, William Jordan, before the U.S. Senate Committee on Agriculture, Nutrition and Forestry on Oct. 21, 2015.

— "Glyphosate did not present genotoxic potential and no evidence of carcinogenicity was observed in rats or mice." **European Food Safety Authority**, *Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate*, 2015

— "In consideration of the strength and limitations of the large body of information on glyphosate … the overall weight of evidence indicates that glyphosate is unlikely to pose a human cancer risk. This is consistent with all other pesticide regulatory authorities world-wide, including the most recent ongoing comprehensive re-evaluation by Germany. …" **Canadian Pest Management Regulatory Authority**, *Proposed Re-Evaluation Decision, PRVD2015-01, Glyphosate*, 2015

Q8. How can agriculture groups and other stakeholders support our legal challenge?

A8. During the public comment period, a broad range of agriculture groups and other stakeholders spoke out in support of glyphosate's history of safe use and in opposition to listing. We encourage these groups to continue to speak publicly about the flaws in Prop 65 and the "Labor Code" mechanism and to underscore the need for glyphosate.

RESOURCES:

- A link to Monsanto's complaint against OEHHA is available here.
- Monsanto.com/glyphosate

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